January 12, 2023 (Updated 01/10/2023)

Washington State Pharmacy Quality Assurance Commission

Commission Business Meeting Materials

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STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Business Meeting
November 17, 2022 – Minutes Draft

Convene: Chair, Teri Ferreira called the meeting to order November 17, 2022, 9:01 AM.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Timothy Lynch, PharmD, MS, FABC, FASHP
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh

Staff:
Shawna Fox, OHP Office Director
Traci Orr, OHP Deputy Director
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support

Commission Members Absent:
William Hayes, PharmD CCHP
Bonnie Bush, Public Member

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – November 17, 2022.

MOTION: Craig Ritchie moved to approve the business meeting agenda for November 17, 2022. Jerrie Allard, second. Motion carries, 11-0.

1.2 OHP Office Director and Deputy Office Director Introductions.

Shawna Fox stepped in as the Office Director of OHP in July 2022. Traci Orr has been serving as Deputy Director since 2021 and has since taken on the role permanently.

1.3 Meeting Minutes Approval – Special Meeting – August 5, 2022.

MOTION: Ken Kenyon moved to approve the special meeting minutes for August 5, 2022. Ann Wolken, second. Motion carries, 11:0.

1.4 Meeting Minutes Approval – Special Meeting – August 24, 2022.

MOTION: Craig Ritchie moved to approve the meeting minutes for August 24, 2022. Ken Kenyon, second. Motion carries, 11:0.

1.5 Meeting Minutes Approval – September 22, 2022.

MOTION: Craig Ritchie moved to approve the meeting minutes for September 22, 2022. Ken Kenyon, second. Motion carries, 11:0.

1.6 Meeting Minutes Approval – September 23, 2022.

MOTION: Craig Ritchie moved to approve the meeting minutes for September 23, 2022. Ken Kenyon, second. Motion carries, 11:0.

2. Consent Agenda.

2.1 Ancillary Utilization Plans Approval.

2.1.1 Aberdeen Health Mart/Aberdeen Pharmacy
2.1.2 Costco Pharmacy
2.1.3 Davenport Good Neighbor Pharmacy
2.1.4 Edmonds Pharmacy
2.1.5 ICHS Bellevue Pharmacy
2.1.6 Island Health Pharmacy
2.1.7 Key Compounding Pharmacy
2.1.8 Lincoln Pharmacy
2.1.9 Makers Pharmacy
2.1.10 Yakima Valley Memorial Pharmacy (North Star Lodge)
2.1.11 RK LTC Pharmacy
2.1.12 Union Avenue Compounding Pharmacy
2.1.13 Valley View Health Center Pharmacy
2.1.14 Yakima Valley Memorial Hospital Pharmacy

2.2 Pharmacy Technician Training Program Approval.

2.2.1 Centralia Pharmacy
2.2.2 Costco Pharmacy
2.2.3 Jefferson Healthcare
2.2.4 Kittitas Valley Healthcare
2.2.5 Makers Pharmacy
2.2.6 Optum Pharmacy
2.2.7 Saars Pharmacy

2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.

Items pulled:

- 2.1.2 Costco Pharmacy
- 2.1.3 Davenport Good Neighbor Pharmacy
- 2.1.5 ICHS Bellevue Pharmacy
- 2.1.10 Yakima Valley Memorial Hospital (North Star Lodge)
- 2.1.14 Yakima Valley Memorial Hospital
- 2.2.4 Kittitas Valley Healthcare
- 2.2.7 Saars Pharmacy

Recusals:

Ann Wolken: **2.2.5, 2.2.6**; Timothy Lynch: **2.1.10, 2.1.14**.

MOTION: Craig Ritchie moved to approve the agenda with the exception of 2.1.2, 2.1.3, 2.1.5, 2.1.10, 2.1.14, 2.2.4, 2.2.7. Patrick Gallaher, second. Motion carries, 11:0.

MOTION: Craig Ritchie moved to approve AUP 2.1.2 Costco Pharmacy. Hawkins DeFrance, second. Motion carries, 11:0.

MOTION: Teri Ferreira moved to approve 2.1.3 Davenport Good Neighbor Pharmacy and 2.1.5 ICHS Bellevue Pharmacy with the recommendation being contingent on the following changes: update old WAC references in 2.1.3 and 2.1.5; update licensure reference from one year to two years in 2.1.5; and add that self-inspection is required within 30 days of change in responsible pharmacy manager in 2.1.5. Craig Ritchie seconds. Motion carries, 11:0.

MOTION: Teri Ferreira moved to approve 2.1.10 and 2.1.14 with the recommendation being contingent on the following changes: to update RCW to tech utilization RCW and update reference to two-year license cycle. 2.1.14's approval is also contingent on updating RCW to tech training program reference in chapter 18.64A RCW. Craig Ritchie, second. Motion carries, 10:0. (Timothy Lynch recused)

MOTION: Ann Wolken moved to approve 2.2.4 and 2.2.7 contingent on approval to add specific policies and procedures. Craig Ritchie, second. Motion carries, 11:0.

NOTE: Consent Agenda matters were tabled due to Public Hearing and resumed after Public Hearings were officially closed.

3. Rulemaking for Reuse and Donation of Unexpired Prescription Drugs (SSB 6526).

3.1 PUBLIC RULES HEARING.

Teri Ferreira, Chair, opened the public rules hearing at 9:21 AM. The purpose of this hearing was to propose adding a new section in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526 (Laws of 2020), an act relating to the reuse and donation of unexpired prescription drugs.

Joshua Munroe provided a brief overview to the commission on the specifics of the CR-102 rule proposal filed under WSR 22-20-100 which introduces rule language for two new proposed sections of rule, WACs 246-945-486 and 246-945-488. Following the briefing the commission opened the floor to comments from interested parties.

Public Comment: George Wang; (Co-Founder of Sirum), testified in support of rules generally, but also provided amendments.

The comment from George Wang was delivered as an oral public comment in addition to previously submitted written comments. These were the only comments received by the commission.

Teri Ferreira, Chair, closed the hearing on WAC 246-945-486 and WAC 246-945-488 at 9:27 AM.

3.2 Approval of Comment Responses and Authorization to File CR-103P (SSB 6526 Rulemaking).

MOTION: Timothy Lynch moved to accept proposed responses as edited today. Craig Ritchie, second. Motion carries, 11:0.

MOTION: Craig Ritchie moved to approve rule language including substantive edit to WAC 246-945-488 on prescriber notification, file supplemental CR-102, schedule public hearing on amended provision. Motion carries, 11:0.

NOTE: Approval of Comment Responses was tabled due to Public Hearing timing and resumed after Public Hearings were officially closed.

4. Rulemaking for the Retired Active Pharmacist License Status.

4.1 PUBLIC RULES HEARING.

Teri Ferreira, Chair, opened the public rules hearing on WAC 246-945-171 at 10:30 AM. The purpose of this hearing was to propose adding a new section in chapter 246-945 WAC to allow retired pharmacists to apply for a retired active pharmacist license status and practice pharmacy in emergent situations or intermittently.

Joshua Munroe provided a brief overview and background information on the issue, noting the importance of the rule language that was approved by the commission and filed with the CR-102 included continuing education requirements.

One written comment was received from an anonymous attendee regarding clarification of the rule.

Teri Ferreria, Chair, closed the hearing on WAC 246-945-171 at 10:34 AM.

4.2 Approval of Comment Responses and Authorization to File CR-103P (Retired Active Pharmacist License Status Rulemaking).

MOTION: Craig Ritchie moved to approve responses to received comments, adopt WAC 246-945-171 and to authorize staff to file CR 103P. Timothy Lynch, second. Motion passes, 11:0

5. Old Business.

5.1 Designation of Presiding Officer for Brief Adjudicative Proceedings.

MOTION: Craig Ritchie moved to approve. Hawkins De France, second. Motion carries, 11:0.

5.2 Revised USP 795 and 797 Update.

Lindsay Trant-Sinclair provided an update stating that staff are aware that the revised USP chapters 795 and 797 are now available and that the new chapters are under review. The revised 795 and 797 will not be official until November 1, 2023. No action deemed necessary by the commission at this time, but the topic will be placed on a future agenda.

Comment from Erika Anderson: Suggested the commission consider a statement on whether early adoption is allowed.

5.3 FAQs from Plan-19 for Review.

Nomi Peaks updated the commission that Plan-19 was removed from the website with the state of emergency coming to an end; however, several FAQs were presented to the commission from Plan-19 that could be posted to the website as they are still relevant without the state of emergency.

MOTION: Timothy Lynch moved to approve FAQs. Craig Ritchie, second. Motion carries, 11:0.

6. Executive Session – CLOSED to the Public.

The commission convened an executive session to discuss with legal counsel representing the commission matters relating to litigation or potential litigation to which the commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the commission pursuant to RCW 42.30.110(1)(i).

7. New Business.

7.1 Out-of- Country Wholesalers.

MOTION: Timothy Lynch moved to reaffirm that the commission does not have authority to issue credentials to out-of-country wholesalers and out-of-country pharmacies. Craig Ritchie, second. Motion carries, 11:0.

7.2 NABP District 8 Resolution.

NABP's District 8 has put forth a resolution for the Pharmacy Quality Assurance Commission to consider supporting.

MOTION: Timothy Lynch moved to decline offer to support. Craig Ritchie, second. Motion carries, 11:0.

7.3 List and Label Request.

The commission has a list and label request to consider approving.

MOTION: Timothy Lynch moved to approve WSPA list and label request. Ken Kenyon, second. Motion carries, 11:0.

7.4 Proposed Changes to 2023 Meeting Dates.

Due to scheduling conflicts, some schedule changes are needed to the 2023 meeting dates.

MOTION: Timothy Lynch moved to approve changes to 2023 meeting dates. Hawkins DeFrance, second, Motion carries, 11:0.

8. Rules and Legislative Updates.

8.1 PQAC Representative(s) for Office of Health Professions 2023 Weekly Legislative Update Call and PQAC Weekly Legislative Calls.

OHP will host its weekly Legislative Update Calls for board and commission members. They have asked for two representatives from each board and commission to attend.

MOTION: Timothy Lynch moved to appoint Craig Ritchie and William Hayes to be PQAC representatives on OHP calls. Jerrie Allard, second. Motion carries, 11:0.

8.2 Update on OTC – only Wholesaler Rulemaking.

Lindsay Trant-Sinclair provided a brief update. This rulemaking has been on hold as other projects have taken precedence. As the FDA is working on rulemaking related to wholesaler requirements, this project will remain on hold until the FDA completes their rulemaking. The commission deemed no action necessary at this time.

8.3 Authorization to Refile Retired Pharmacist Emergency Rule.

The commission has emergency rules on the retired active pharmacist license status under WSR 22-20-023 that will expire in January 2023.

MOTION: Craig Ritchie moved to refile emergency rule and withdraw when permanent rule is in effect. Ken Kenyon, second. Motion carries, 11:0.

8.4 Proposed Update to Incorporation of 21 CFR in WAC 246-945-040.

WAC 246-945-040 not only incorporates 21 CFR, but it also excludes certain sections. Updates were needed to which sections the commission is both incorporating and not incorporating in WAC 246-945-040.

MOTION: Craig Ritchie moved to approve amended rule language with proposed attachment inserted and file CR-105. Patrick Gallaher, second. Motion carries, 11:0.

8.5 Accessible Labeling Rulemaking – Survey Data Review.

In October 2022, staff completed and conducted a survey to determine current practices and identified barriers by licensees related to accessible prescription information services to patients.

Joshua Munroe presented an overview of the survey and the data collected, as well as a brief updated report on state-level actions related to providing visually accessible and translated prescription information services.

Commision Comments:

Craig Ritchie: Noted concern that there are a few respondents who reported that the reason they are not participating is that it is not required by law.

Jerrie Allard: Suggested assigning to Pharmacy Practice Subcommittee to assist staff.

Teri Ferreira: Would like further review of Nevada language.

Staff Comments:

Lindsay Trant-Sinclair: There is no specific action needed at this time, a good next step would be to narrow down a starting point for the draft rule language. Any guidance that could be provided to staff to start a rough outline of what the rule language might look like would be helpful. We would like to bring an outline back to full commission for review before assigning to Pharmacy Practice subcommittee.

Stakeholder comments:

Doreen Cornwell: Anecdotal experience with the blind is that folks are not aware that accommodations are an option. Issue when labels are provided separate from medications. Rule language is not going to be perfect at first, need to get information from vetted source.

Marci Carpenter, President of the National Federation of the Blind: In discussing the issue of non-visual access, found that majority of people do not ask because they are not aware it is possible to get accommodation.

David Streeter, **WSHA:** Raised a question on incomplete responses and why, and how many were of those respondents were from hospital settings. Streeter noted interest in helping to get a larger pool of respondents from hospital settings.

Joana Ramos: Results should be disaggregated by setting. Distinction between translation (written) and translator (verbal). DSHS offers some translation services, but only in six languages.

En-Vision America: Reported cost data is in a very large range because there are many different possibilities. Costs really depend on services provided.

9. Panel Review – Study Plan.

MOTION: Jerrie Allard moved to approve Patrick Gallaher, Judy Guenther, and Teri Ferreira as the panel reviewing and approving/denying the study plans. Craig Ritchie, second. Motion carries, 11:0.

9.1 PHRM.PH.61278050.

MOTION: Teri Ferreira moved to approve study plan as presented. Patrick Gallaher, second. Motion carries, 3:0.

9.2 PHRM.PH.61188090.

MOTION: Teri Ferreira moved to approve study plan as presented. Patrick Gallaher, second. Motion carries, 3:0.

9.3 PHRM.PH.61176247.

MOTION: Teri Ferreira moved to approve study plan as presented. Patrick Gallaher, second. Motion carries, 3:0.

10. Open Forum.

Public Comment: Richard Molitor brought to attention that for the second year in a a row, NAPLEX scoring has had issues resulting in applicants receiving a false failing score. He would like to encourage the commission to stay abreast of the matter so that it does not happen again and that NABP remain transparent.

Marlee O'Neill confirms that the commission is aware of the issue and is working with NABP.

11. Commision Member Reports.

11.1 Pharmacy Practice Subcommittee Report – Craig Ritchie, Subcommittee Chair.

The Pharmacy Practice Subcommittee was unable to meet on its scheduled date of November 8, 2022, due to inclement weather. Revisions to the Sample AUP document and the definition of stocking as it relates to the pharmacy assistant's scope of practice were the two topics designated for discussion. The Pharmacy Practice Subcommittee meeting rescheduled date is still pending. The program staff will provide this information via GovDelivery and on the commission's webpage once finalized.

11.2 Legislative Subcommittee Report Out – Craig Ritchie (for William Hayes, Subcommittee Chair).

The Legislative Subcommittee met on October 7, 2022, to discuss if any bill proposals should be considered for the 2024 legislative session. At the June 2022 subcommittee meeting, commission staff was tasked with looking into the practice of "white bagging." The Facilities Subcommittee will take up the conversation around rulemaking on white bagging at their next scheduled meeting.

11.3 Compounding Subcommittees Report – Hawkins DeFrance, Subcommittee Chair.

The Compounding Subcommittee engaged stakeholders and interested parties in a lively discussion regarding the directive entitled *Nonresident Pharmacy: Approved List of Recognized States.* Stakeholder feedback was reviewed and discussed during the September meeting. The subcommittee members then conducted an additional analysis of the states. The results returned to the PQAC program staff for information gathering in preparation for the next subcommittee meeting in December.

11.4 Open discussion related to items or issues relevant to commission business/pharmacy practice.

Hawkins DeFrance attended the FDA IGA conference and noted one topic of concern. The FDA has raised an alarm about mobile IV clinics and that these clinics are compounding without following <797>. He suggests asking staff to work with WMC and NCQAC to come up with ways of enforcing <797>.

Ken Kenyon suggests considering an agenda item for the next business meeting regarding expectations of transfer prescriptions and time to fill new prescriptions.

12. Staff Reports.

12.1 Executive Director – Marlee O'Neill.

The State Office audit of the Prescription Monitoring Program was completed was completed and posted in early October. The commission will also be working on continuing education but at this time no further action is required.

12.2 Deputy Director – Lindsay Trant-Sinclair.

Staff made changes to the Uniform Facilities Enforcement Framework (UFEF) after the September business meeting. The current draft of the proposed legislation is under review at the Governor's office.

The AA3 position has been filled and the new employee will be joining on December 16, 2022.

In regard to commissioner recruitment, the packet for the pharmacist candidate is under review and should be with the Governor's office soon.

12.3 Assistant Attorney General – Christopher Gerard.

Nothing to report.

13. Summary of Meeting Action Items.

- Follow up with contingent AUP and TTP approvals
- 3.2 – Staff will file a supplemental CR-102 on WAC 246-945-486 and -488, reuse and donation of unexpired prescription drugs
- 4.2 – Staff will file a CR-103 on WAC 246-945-171, retired active pharmacist license status
- 5.1 – Staff will make changes to the BAP designation of presiding officer
- 5.2 – Staff will review the revised 795 and 797 and bring that information back to the commission at a future meeting
- 5.3 – Staff will post the FAQs taken from Plan-19 that are still relevant
- 7.1 – Communicate the commission's position on out-of-country wholesalers and out of country pharmacies to credentialing
- 7.2 – Report back to NABP on commission's position on resolution 8
- 7.3 – Convey commission's decision on WSPA list and label request to public disclosure unit
- 7.4 – File new 2023 meeting dates with the code reviser's office and adjust calendar holds for 2023
- 8.1 – Notify OHP that Craig Ritchie and William Hayes are PQAC's representatives on the OHP weekly calls and send out calendar hold for PQAC's Friday calls
- 8.3 – Refile retired active pharmacist license status emergency rule and withdraw it when the permanent rule becomes effective
- 8.4 – File the CR-105 to update the incorporation by reference on title 21 CFR with the amended language as shown today

- 8.5 – Put together outline of feedback today on accessible labeling rule language to inform initial draft of rule language
- 9 – Notify credentialing of approvals to reexam for applicants presented today11.4 – Reach out to WMC and NCQAC to get more information on IV infusion clinics and add future agenda item for increased times for prescription transfer at pharmacies

Teri Ferreira thanked all of commissioners, staff, licensees, and stakeholders for their preparation and participation in PQAC business meetings.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 3:23 PM.

Read this page carefully

WA Pharmacy Quality Assurance Commission

Pharmacy Self-Inspection Worksheet

~~2022~~ 2023 USP 797 – Sterile Compounding Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March and~~or~~ within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. The following addendum is required to be filled out and kept on file with the General Pharmacy or Hospital Pharmacy Self-Inspection Worksheet. **Do not send to the commission office.**

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The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace U.S. Pharmacopeia (USP) <797> Pharmaceutical Compounding – Sterile Preparations. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

If you are an early adopter of USP chapter 800 under PQAC Policy Statement #60 - Regulation of the Handling of Hazardous Drugs, Questions 43, 56, and 72 you may answer N/A to the USP <797> requirement. However, a requirement statement from USP <800> has been added in blue.

Date responsible manager/change of responsible manager inspection was performed: Click or tap to enter a date.

Signature of responsible pharmacy manager: Click or tap here to enter text._____

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

General Rule Reference - Applies to all questions through worksheet.

RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Standard Operating Procedures						
☐	☐	☐	1	**The permitted pharmacy listed above shall have a written, properly approved, Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in USP <797> are to be met.**	USP Chapter 797 - Suggested Standard Operating Procedures. "The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared."	Click or tap here to enter text.
Compounding Personnel						
				Documentation is on file for EACH person who compounds sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities:	USP Chapter 797 - "The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties. a. perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces; b. select and appropriately don protective garb; c. maintain or achieve sterility of CSPs in ISO 5 PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs (see Hazardous Drugs as CSPs and Radiopharmaceuticals as CSPs); d. identify, weigh, and measure ingredients; e. manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs."	Click or tap here to enter text.
☐	☐	☐	2	**Perform aseptic hand cleansing;**		
☐	☐	☐	3	**Perform disinfection of compounding surfaces;**		
☐	☐	☐	4	**Select and appropriately don protective garb;**		
☐	☐	☐	5	**Maintain or achieve sterility of CSPs;**		
☐	☐	☐	6	**Identify, weigh and measure ingredients;**		
☐	☐	☐	7	**Manipulate sterile products aseptically;**		
☐	☐	☐	8	**Label and quality inspect CSPs.**		
Personnel Training and Competency						
☐	☐	☐	9	**Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in**	USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				the theoretical principles, practical skills of aseptic manipulations.	and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	
☐	☐	☐	10	**Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see Table 1) environmental conditions, and cleaning and disinfection procedures. USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	Click or tap here to enter text.
☐	☐	☐	11	**Personnel perform didactic review, pass written and media-fill testing of aseptic work skills initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi- annually for high-risk level.**	USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills - "Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding."	Click or tap here to enter text.
☐	☐	☐	12	**Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re- evaluated to ensure correction of all aseptic work practice deficiencies; personnel pass all evaluations prior to resuming compounding.**	USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills - "Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	13	**Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in addition to didactic evaluation of aseptic media fill and glove tip testing.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures."	Click or tap here to enter text.
☐	☐	☐	14	**Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record.**	USP Chapter 797- Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Garbing and Gloving Competency Evaluation - "Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see Personnel Cleansing and Garbing under Personnel Training and Evaluation in Aseptic Manipulation Skills above). The visual observation shall be documented on a form such as the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel (see Appendix III) and maintained to provide a permanent record and long-term assessment of personnel competency."	Click or tap here to enter text.
☐	☐	☐	15	**Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding.**	USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Gloved Fingertip Sampling - "All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use."	Click or tap here to enter text.
☐	☐	☐	16	**All compounding personnel have technique and competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.**	USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Aseptic Manipulation Competency Evaluation - "After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
CSP Microbial Contamination: Low-Risk Level CSPs						
☐	☐	☐	17	**The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices."	Click or tap here to enter text.
☐	☐	☐	18	**Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products and not more than 2 entries into any container.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP."	Click or tap here to enter text.
☐	☐	☐	19	**Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 3. Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile products, and containers for storage and dispensing."	Click or tap here to enter text.
☐	☐	☐	20	**In the absence of sterility tests, storage is not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°, or per manufacturer guidelines.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 4. For a low-risk level preparation, in the absence of passing a sterility test (see Sterility Tests <71>), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), for not more than 14 days at a cold temperature (see General Notices and Requirements), and for 45 days in solid frozen state between - 25° and -10°."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
CSP Microbial Contamination: Low-Risk Level CSPs with 12-Hour or Less Beyond-Use Date (BUD)						
☐	☐	☐	21	**PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "1. PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified and maintain ISO Class 5 as described in Facility Design and Environmental Controls for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination."	Click or tap here to enter text.
☐	☐	☐	22	**The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse or food preparation.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive."	Click or tap here to enter text.
☐	☐	☐	23	**Sinks are not located within one meter of the ISO Class 5 PEC.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "3. Personnel shall follow the procedures described in Personnel Cleansing and Garbing and Additional Personnel Requirements prior to compounding. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device."	Click or tap here to enter text.
CSP Microbial Contamination: Medium-Risk Level CSPs						
☐	☐	☐	24	**Product considered medium risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions."	Click or tap here to enter text.
☐	☐	☐	25	**Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					risk of contamination. 2. The compounding process includes complex aseptic manipulations other than the single-volume transfer."	
☐	☐	☐	26	**In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in a frozen state of -25° to - 10°, or per manufacturer guidelines.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 4. In the absence of passing a sterility test (see Sterility Tests USP Chapter 71), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see General Notices and Requirements), for not more than 9 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	Click or tap here to enter text.
☐	☐	☐	27	**Products considered medium-risk if aseptic manipulations within an ISO Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.**	USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - Medium-Risk Level CSPs - "Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs."	Click or tap here to enter text.
Immediate Use CSPs						
☐	☐	☐	28	**Immediate-use CSPs are used only when there is a need for emergency or immediate patient administration of a CSP, where administration can begin with 1 hour of start of compounding.**	USP Chapter 797 Immediate-Use CSPs - "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. … 4. Administration begins not later than 1 hour following the start of the preparation of the CSP."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	29	**Product considered immediate-use only if the compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than 2 entries into any one container or package of sterile infusion solution or administration container/device.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile-nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration con-trainer/device. For example, anti neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs."	Click or tap here to enter text.
☐	☐	☐	30	**Aseptic technique is followed and if not immediately administered, CSP is continually supervised.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces."	Click or tap here to enter text.
☐	☐	☐	31	**Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounder, and the exact 1-hour BUD and time.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	32	**Administration begins not later than 1 hour following the start of the preparation of the CSP; If administration has not begun within 1 hour of being compounded, CSP is discarded.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low- Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1 hour BUD and time."	Click or tap here to enter text.
Single-Dose and Multiple-Dose Containers						
☐	☐	☐	33	**Single-dose containers are used within 1 hour of entry when opened or removed in worse than ISO Class 5 air quality.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see Table 1) air quality (see Immediate-Use CSPs), and any remaining contents must be discarded."	Click or tap here to enter text.
☐	☐	☐	34	**Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry, if vial is kept inside the PEC.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Single-dose vials exposed to ISO Class 5 (see Table 1) or cleaner air may be used up to 6 hours after initial needle puncture."	Click or tap here to enter text.
☐	☐	☐	35	**Opened single-dose ampules are not stored.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened single-dose ampules shall not be stored for any time period."	Click or tap here to enter text.
☐	☐	☐	36	**Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, or as specified by the manufacturer, whichever is less.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing USP Chapter 51) unless otherwise specified by the manufacturer."	Click or tap here to enter text.
Hazardous Drugs as CSPs						
☐	☐	☐	37	**Hazardous drugs are prepared for administration only under conditions**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be prepared for administration only under	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				that protect the healthcare workers and other personnel in the preparation and storage areas.	conditions that protect the healthcare workers and other personnel in the preparation and storage areas."	
☐	☐	☐	38	**Hazardous drugs are stored separately from other inventory.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure."	Click or tap here to enter text.
☐	☐	☐	39	**Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal."	Click or tap here to enter text.
☐	☐	☐	40	**Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place and follows aseptic practices specified for the appropriate contamination risk levels.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter."	Click or tap here to enter text.
☐	☐	☐	41	**Access is limited to areas where hazardous drugs are stored and prepared.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation."	Click or tap here to enter text.
☐	☐	☐	42	**All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All hazardous drugs shall be prepared in a BSC3 or a CACI that meets or exceeds the standards for CACI in this chapter."	Click or tap here to enter text.
Hazardous Drugs as CSPs						
☐	☐	☐	43	**The ISO Class 5 BSC or CACI is placed in an ISO Class 7 area, physically separated and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas.** **Early adopters of USP 800 pursuant to PQAC Policy #60: The ISO Class 5 C-PEC is placed in either an ISO Class 7 ante-room or an unclassified**	USP Chapter 797 - Hazardous Drugs as CSPs - "The ISO Class 5 (see Table 1) BSC or CACI shall be placed in an ISO Class 7 (see Table 1) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see Table 1) or better ante-areas, thus providing inward airflow to contain any airborne drug."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				containment segregated compounding area (C-SCA). If using a C- SCA, the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.		
☐	☐	☐	44	**A pressure indicator is installed that can be readily monitored for correct room pressurization.**	USP Chapter 797 - Hazardous Drugs as CSPs - "A pressure indicator shall be installed that can be readily monitored for correct room pressurization."	Click or tap here to enter text.
☐	☐	☐	45	**If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI.**	USP Chapter 797 - Hazardous Drugs as CSPs - "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI."	Click or tap here to enter text.
☐	☐	☐	46	**Personal protective equipment is worn when compounding.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices."	Click or tap here to enter text.
☐	☐	☐	47	**Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs."	Click or tap here to enter text.
☐	☐	☐	48	**Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually.**	USP Chapter 797 - Hazardous Drugs as CSPs - "This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually."	Click or tap here to enter text.
☐	☐	☐	49	**Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	50	**Disposal of hazardous waste complies with all applicable federal and state regulations.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	Click or tap here to enter text.
☐	☐	☐	51	**Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All personnel who per-form routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	Click or tap here to enter text.
Environmental Quality and Control						
Facility Design and Environmental Controls						
☐	☐	☐	52	**Critical sites are only exposed to ISO Class 5 or cleaner air.**	USP Chapter 797 - Environmental Quality and Control - Exposure of Critical Sites - "Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see Table 1) air."	Click or tap here to enter text.
☐	☐	☐	53	**Compounding facility provides a comfortable and well- lighted working environment.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, …"	Click or tap here to enter text.
☐	☐	☐	54	**Facility has current certification documenting that PECs maintain ISO Class 5 and meet airflow requirements.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					whenever the device or room is relocated or altered or major service to the facility is performed."	
☐	☐	☐	55	**Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs."	Click or tap here to enter text.
☐	☐	☐	56	**Facility has current certification documenting that the buffer area maintains ISO Class 7 conditions with an ACPH of not less than 30.** **Early adopters of USP 800 pursuant to PQAC Policy #60: If using an unclassified containment segregated compounding area (C-SCA), the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30."	Click or tap here to enter text.
☐	☐	☐	57	**A minimum differential positive pressure of 0.02- to 0.05- inch water column is used for rooms providing a physical separation through the use of walls, doors and pass- through.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "For rooms providing a physical separation through the use of walls, doors, and pass-through, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required."	Click or tap here to enter text.
☐	☐	☐	58	**Displacement airflow is employed for buffer areas not physically separated from the ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "For buffer areas not physically separated from the ante-areas, the principle of displacement air-flow shall be employed."	Click or tap here to enter text.
☐	☐	☐	59	**Adeqate HEPA-filtered airflow is supplied to the buffer area and ante-area.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	60	**Facility has current certification documenting that ante- area maintains ISO Class 8 conditions with an ACPH of not less than 30.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas." USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed." USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Quality and Control - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts - "ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area."	Click or tap here to enter text.
☐	☐	☐	61	**For nuclear buffer areas, facility has current certification documenting that the buffer area maintains ISO Class 8 conditions.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements." USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	Click or tap here to enter text.
☐	☐	☐	62	**If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				filters is adequate, providing the combined ACPH not less than 30.	of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30."	
☐	☐	☐	63	**Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are nonpermeable, nonshedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.	Click or tap here to enter text.
☐	☐	☐	64	**The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and nonshedding; the surfaces are resistant to damage by disinfectant agents.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents."	Click or tap here to enter text.
☐	☐	☐	65	**Junctures of ceilings to walls are coved or caulked.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate."	Click or tap here to enter text.
☐	☐	☐	66	**If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked around each perimeter.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame."	Click or tap here to enter text.
☐	☐	☐	67	**The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	68	**The buffer area does not contain sources of water (sinks) or floor drains.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - The buffer area shall not contain sources of water (sinks) or floor drains.	Click or tap here to enter text.
☐	☐	☐	69	**Works surfaces are constructed of smooth, impervious materials**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected."	Click or tap here to enter text.
☐	☐	☐	70	**Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility."	Click or tap here to enter text.
☐	☐	☐	71	**Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection."	Click or tap here to enter text.
Placement of Primary Engineering Controls						
☐	☐	☐	72	**PECs are located within a restricted access ISO Class 7 buffer area unless an exception met. Exceptions:** • **Only authorized personnel and materials required for compounding and cleaning shall be permitted in buffer area** • **Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than Class 8 environment.** • **PECS shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.**	USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls - "PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1), with the following CAI/CACI exceptions below: Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment. PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				Early adopters of USP 800 pursuant to PQAC Policy #60: If using an unclassified containment segregated compounding area that complies with USP 800.		
☐	☐	☐	73	**When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed.**	USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls - "When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations."	Click or tap here to enter text.
☐	☐	☐	74	**A pressure gauge or velocity meter is installed to monitor the pressure differential or air-flow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area; results are reviewed and documented in a log at least every work shift (minimum daily) or by a continuous recording device.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - "A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante- area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device."	Click or tap here to enter text.
☐	☐	☐	75	**The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa -0.02 inch water column.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - "The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column)."	Click or tap here to enter text.
☐	☐	☐	76	**In facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meters/second (40 feet per minute) between buffer area and ante-area, when buffer area is not physically separated from ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Additional Personnel Requirements						
☐	☐	☐	77	**Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present."	Click or tap here to enter text.
Cleaning and Disinfecting the Compounding Area						
☐	☐	☐	78	**When compounding activities require the manipulation of patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation and are controlled by specific SOPs to avoid any cross-contamination.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross- contamination."	Click or tap here to enter text.
☐	☐	☐	79	**When possible, packaged compounding supplies and components are uncartoned and wiped down with a disinfectant that does not leave a residue in an ante-area ISO Class 8 air quality, before being passed into buffer areas; Supplies are allowed to dry before compounding.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see Table 1) air quality, before being passed into the buffer areas."	Click or tap here to enter text.
☐	☐	☐	80	**For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are included in written SOPs and are followed by all compounding personnel.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see Table 1) compounding areas for exposure of critical sites as well as buffer areas, ante areas, and segregated compounding areas All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	81	**LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known or suspected.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches."	Click or tap here to enter text.
☐	☐	☐	82	**Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality."	Click or tap here to enter text.
☐	☐	☐	83	**Floors in ISO Class 7 and 8 areas are cleaned daily while you are not actively compounding; mopping is performed by trained personnel using approved agents and written procedures.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs."	Click or tap here to enter text.
☐	☐	☐	84	**In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly."	Click or tap here to enter text.
☐	☐	☐	85	**All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area,	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				removed from these areas except for disposal.	ante- area, and segregated compounding areas and shall not be re- moved from these areas except for disposal."	
☐	☐	☐	86	**If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned."	Click or tap here to enter text.
☐	☐	☐	87	**Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point."	Click or tap here to enter text.
☐	☐	☐	88	**No particle-generating material is used to disinfect the sterile entry points of packages and devices.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Sterile 70% IPA wetted gauze pads or other particle- generating material shall not be used to disinfect the sterile entry points of packages and devices."	Click or tap here to enter text.
☐	☐	☐	89	**No shipping cartons are taken into the buffer area, clean area or segregated compounding area.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area."	Click or tap here to enter text.
Personnel Cleansing and Garbing						
☐	☐	☐	90	**Personal hand hygiene and garb procedures are performed in ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. … Before entering the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), com-pounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed."	
☐	☐	☐	91	**Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied."	Click or tap here to enter text.
☐	☐	☐	92	**Don shoe covers one at a time placing covered shoe on clean side line of demarcation.** ***This is considered a best practice.***		Click or tap here to enter text.
☐	☐	☐	93	**PPE is donned in an order that proceeds from activities considered dirtiest to cleanest: Garb and cleansing in ante-area as follows: Dirty garb (shoes or shoe covers, head and facial hair covers, face mask) Hand hygiene (fingernail cleansing, hand and forearm washing and drying), Clean garb nonshedding gown.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields."	Click or tap here to enter text.
☐	☐	☐	94	**Cleansing and gloving in buffer room or area as follows: hand cleansing with a surgical alcohol-based product with persistent activity, allow hands to dry, don sterile gloves and apply sterile 70% IPA.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Once inside the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	95	**Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Routine application of sterile 70%IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched."	Click or tap here to enter text.
☐	☐	☐	96	**Gloves are inspected for holes and replaced when breaches are detected.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected."	Click or tap here to enter text.
☐	☐	☐	97	**Only exterior gown used for non-hazardous compounding maybe removed and redonned in the ante area during the work shift if not visibly soiled. It is suggested that gowns be redonned only if they are removed and retained on the clean side of the line of demarcation in the ante area.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be redonned during that same work shift only."	Click or tap here to enter text.
Elements of Quality Control						
☐	☐	☐	98	**A written description of specific training and performance evaluations for compounding personnel is developed for each site.**	USP Chapter 797 - Environmental Quality and Control - "A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site."	Click or tap here to enter text.
☐	☐	☐	99	**Facility follows procedures for physical inspection of all sterile drugs and devices**		Click or tap here to enter text.
☐	☐	☐	100	**If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk.**	USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk."	Click or tap here to enter text.
☐	☐	☐	101	**Bulk or unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and**	USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				lighting conditions that are either indicated in the official monographs or approved by suppliers.	containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers."	
☐	☐	☐	102	**All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined by the device's manufacturer or any regulations that govern the use of that device.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits."	Click or tap here to enter text.
☐	☐	☐	103	**For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of calibration, annual maintenance, monitoring for proper function, and procedures for use.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs."	Click or tap here to enter text.
☐	☐	☐	104	**Personnel are appropriately trained to operate any equipment they use while compounding and are trained to determine if the device is operating properly or is malfunctioning.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning."	Click or tap here to enter text.
☐	☐	☐	105	**Results from equipment maintenance and calibration are kept for the lifetime of the equipment.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment."	Click or tap here to enter text.
Viable and Non-Viable Environmental Sampling						
☐	☐	☐	106	**For low-risk level CSPs with 12-hour or less BUD prepared in a PEC that maintains an ISO Class 5 sampling, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5.**	USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Viable Air Sampling - "For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see Table 1), air sampling shall be performed at locations inside the ISO Class 5 (see Table 1) environment and other areas that are in close proximity to	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					the ISO Class 5 (see Table 1) environment during the certification of the PEC."	
☐	☐	☐	107	**A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually.**	USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Air Sampling Devices - "Sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity."	Click or tap here to enter text.
☐	☐	☐	108	**Engineering control performance verification is performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered or major service to the facility is performed. (Nonviable)**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Engineering Control Performance Verification - "PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	Click or tap here to enter text.
☐	☐	☐	109	**Total particle counts are performed by a qualified operator using state-of-the-art electronic equipment and are within established guidelines in each ISO classified area no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. (Nonviable)**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts - "Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	110	**An appropriate environmental sampling plan is in place for airborne viable particles, is performed at least every 6 months, and includes locations within each ISO class 5 environments and in the ISO class 7 and 8 areas.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan - "An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes)."	Click or tap here to enter text.
☐	☐	☐	111	**The sampling plan for airborne particles includes sample location, method of collection, frequency of sampling, volume of air sampled, time of day as related to activity in the compounding area and action levels.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan - "The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels."	Click or tap here to enter text.
☐	☐	☐	112	**A general microbiological growth medium supplemented with additives to neutralize the effects of disinfecting agents is used to support the growth of bacteria.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium - "A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria."	Click or tap here to enter text.
☐	☐	☐	113	**Surface sampling is performed in all ISO classified areas on a periodic basis to evaluate cleaning and disinfecting procedures and employee competency in work practices.**	USP Chapter 797 - Environmental Quality and Control - Surface Cleaning and Disinfection Sampling and Assessment - "Surface sampling shall be performed in all ISO classified areas on a periodic basis."	Click or tap here to enter text.
☐	☐	☐	114	**Sampling data is collected and reviewed on a routine basis as a means of evaluating overall control of the compounding environment.**	USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation - "Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment."	Click or tap here to enter text.
☐	☐	☐	115	**When microbial sampling exceeds action levels, procedures and practices are reviewed.**	USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation - "Any cfu count that exceeds its respective action level (see Table	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					4) should prompt a reevaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted."	
☐	☐	☐	116	**Regardless of the number of cfu identified in each sample, microorganisms recovered must be identified at least by genus level by an appropriate credentialed laboratory.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Action Levels, Documentation, and Data Evaluation - "Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are deter-mined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in Table 2 should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler."	Click or tap here to enter text.
☐	☐	☐	117	**In high risk environments, growth media also supports the growth of fungi.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium - "Malt extractagar or some other media that supports the growth of fungi shall be used in high- risk level compounding environments."	Click or tap here to enter text.
Verification of Automated Compounding Devices for Parenteral Nutrition						
☐	☐	☐	118	**Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested.**	USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Accuracy - "Thus, their testing procedures shall be verified to meet the USP requirements stated in the individual monograph for the component being tested."	Click or tap here to enter text.
☐	☐	☐	119	**Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals.**	USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Precision - "Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					at weekly intervals to avoid potentially clinically significant cumulative errors over time."	
Finished Preparation Release Checks and Tests						
☐	☐	☐	120	**All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Inspection of Solution Dosage Forms and Review of Compounding Procedures - "All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed."	Click or tap here to enter text.
☐	☐	☐	121	**A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Compounding Accuracy Checks - "Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release."	Click or tap here to enter text.
Storage and Beyond-Use Dating						
☐	☐	☐	122	**Personnel who prepare, dispense and administer CSPs store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs.**	USP Chapter 797 Storage and Beyond-Use Dating - "Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs."	Click or tap here to enter text.
☐	☐	☐	123	**If CSPs are distributed to and administered in other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions is considered when assigning BUDs.**	USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates - "When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions shall be considered when assigning BUDs."	Click or tap here to enter text.
☐	☐	☐	124	**The controlled temperature areas are monitored at least once daily and results are documented.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	125	**Facilities have policies and procedures governing the determination of BUDs.**	USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates - "To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products."	Click or tap here to enter text.
☐	☐	☐	126	**Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations."	Click or tap here to enter text.
☐	☐	☐	127	**Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long."	Click or tap here to enter text.
Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs						
☐	☐	☐	128	**The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - "Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility."	Click or tap here to enter text.
☐	☐	☐	129	**Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Packaging, Handling, and Transport - "Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	130	**Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location."	Click or tap here to enter text.
☐	☐	☐	131	**Outdated and unused CSPs are appropriately disposed.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "Outdated and unused CSPs shall be returned to the compounding facility for disposition."	Click or tap here to enter text.
☐	☐	☐	132	**SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "SOPs must exist to ensure that storage conditions in the patient care setting are suitable for the CSP specific storage requirements."	Click or tap here to enter text.
☐	☐	☐	133	**Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs - "The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients)."	Click or tap here to enter text.
☐	☐	☐	134	**If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs - "Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients."	Click or tap here to enter text.
☐	☐	☐	135	**A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs.**	USP Chapter 797 - Patient or Caregiver Training - "A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs."	Click or tap here to enter text.
Patient Monitoring and Adverse Events Reporting						
☐	☐	☐	136	**SOPs are available that describe the means for patients or other recipients**	USP Chapter 797 - Patient Monitoring and Adverse Events Reporting - "The SOP manuals of compounding facilities	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.	shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs."	
☐	☐	☐	137	**Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors.**	USP Chapter 797 - Patient Monitoring and Adverse Events Reporting - "Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences."	Click or tap here to enter text.
Quality Assurance Program						
☐	☐	☐	138	**Media-fill test procedure with appropriate risk level prepared or equivalent test is performed at least annually by personnel.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding."	Click or tap here to enter text.
☐	☐	☐	139	**Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPS - Quality Assurance - "Quality assurance practices include, but are not limited to the following: Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	Click or tap here to enter text.
☐	☐	☐	140		USP Chapter 797 - Quality Assurance (QA) Program - "A provider of CSPs shall have in place a formal QA program	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes.	intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter."	
CSP Microbial Contamination: High-Risk Level CSPs						
☐	☐	☐	141	**Sterilize high-risk CSPs.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - "High-risk level CSPs must be sterilized before being administered to patients."	Click or tap here to enter text.
☐	☐	☐	142	**If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound.**	USP Chapter 797 CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 3. Compounding personnel are improperly garbed and gloved (see Personnel Cleansing and Use of Barrier Protective Equipment)."	Click or tap here to enter text.
☐	☐	☐	143	**Product considered high-risk if any nonsterile ingredients or devices are used.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization."	Click or tap here to enter text.
☐	☐	☐	144	**Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour (see Immediate-Use CSPs): sterile contents of commercially manufactured products, CSPs that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs."	Click or tap here to enter text.
☐	☐	☐	145	**Product considered high-risk if Nonsterile water- containing preparations are stored for more than 6 hours before being sterilized.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 4. Nonsterile water-	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					containing preparations are stored for more than 6 hours before being sterilized."	
☐	☐	☐	146	**The date of receipt of nonsterile components is clearly and indelibly marked on each package.**	USP Chapter 797 - Elements of Quality Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient."	Click or tap here to enter text.
☐	☐	☐	147	**Sterilization methods are verified to achieve sterility for the quantity and type of containers.**	USP Chapter 797 - Responsibility of Compounding Personnel - "The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging."	Click or tap here to enter text.
☐	☐	☐	148	**Media-fill test procedure or equivalent test is performed at least semi-annually by personnel.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance - "In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs."	Click or tap here to enter text.
☐	☐	☐	149	**Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance - "Quality Assurance procedures for high-risk level CSPs include all those for low-risk level CSPs." USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs - Quality Assurance - "Quality assurance practices include, but are not limited to the following: Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	
☐	☐	☐	150	**Allowable limits for bacterial endotoxins are met.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing - "In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration."	Click or tap here to enter text.
☐	☐	☐	151	**High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing - "All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."	Click or tap here to enter text.
☐	☐	☐	152	**If high-risk level CSPs are dispensed before receiving the results of their sterility tests, there is a written procedure requiring daily observation of incubating test specimens.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing - "When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens."	Click or tap here to enter text.
☐	☐	☐	153	**High-risk level CSPs must be pyrogen tested, excluding those for inhalation or ophthalmic administration, if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing - "All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8°	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see USP Chapter 85 - Bacterial Endotoxins Test and USP Chapter 151 - Pyrogen Test)."	
☐	☐	☐	154	**All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2. µm preceding or during filing into their final containers to remove particulate matter. Sterilization of high- risk level CSPs by filtration shall be performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 or superior air quality environment."	Click or tap here to enter text.
☐	☐	☐	155	**CSP maintains acceptable strength, purity and integrity of containers after sterilization.**	USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization."	Click or tap here to enter text.
☐	☐	☐	156	**In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "For sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see General Notices and Requirements), for not more than 3 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	Click or tap here to enter text.
☐	☐	☐	157	**Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "[NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]"	Click or tap here to enter text.
Verification of Compounding Accuracy and Sterility (High-Risk Compounding)						
☐	☐	☐	158	**Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - "Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	159	**The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs are confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling with certificates of analysis provided by suppliers.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - "The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers."	Click or tap here to enter text.
☐	☐	☐	160	**The licensed healthcare professional is responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality and packaging integrity of CSPs.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - "The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see Methods of Sterilization under USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs."	Click or tap here to enter text.
☐	☐	☐	161	**Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids."	Click or tap here to enter text.
☐	☐	☐	162	**Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm."	Click or tap here to enter text.
☐	☐	☐	163	**Sterile filters used are certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta on each square centimeter of upstream filter surface area.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs)."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	164	**The compounding supervisor ensures that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP."	Click or tap here to enter text.
☐	☐	☐	165	**The filter dimensions and liquid material to be sterile- filtered permit the sterilization process to be completed rapidly, without replacement of the filter during the process.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process."	Click or tap here to enter text.
☐	☐	☐	166	**When CSPs are known to contain excessive particulate matter, a prefilter of larger-porosity membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter."	Click or tap here to enter text.
☐	☐	☐	167	**Filter units used are subjected to manufacturers' recommended integrity test.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test."	Click or tap here to enter text.
☐	☐	☐	168	**Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized."	Click or tap here to enter text.
☐	☐	☐	169	**The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High- Risk Level CSPs by Steam - "The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	170	**The effectiveness of steam sterilization is verified using appropriate BIs of Bacillus stearothermophilus and other confirmation methods.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Steam - "The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see USP Chapter 1229.5 - Biological Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	Click or tap here to enter text.
☐	☐	☐	171	**Heated filtered air is evenly distributed throughout the chamber by a blower device; the oven is equipped with a system for controlling temperature and exposure period.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "Heated filtered air shall be evenly distributed throughout the chamber by a blower device."	Click or tap here to enter text.
☐	☐	☐	172	**Dry heat is used only for those materials that cannot be sterilized by steam.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable."	Click or tap here to enter text.
☐	☐	☐	173	**During sterilization, sufficient space is left between materials to allow for good air circulation.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air."	Click or tap here to enter text.
☐	☐	☐	174	**The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	Click or tap here to enter text.
☐	☐	☐	175	**The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other confirmation methods.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see USP Chapter 1229.5 - Biological	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	
☐	☐	☐	176	**The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat - "The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility."	Click or tap here to enter text.
☐	☐	☐	177	**The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs); the bacterial endotoxin test is performed on the ECVs to verify that the cycle is capable of achieving a 3- log reduction in endotoxin.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat - "The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 85 - Bacterial Endotoxins Test)."	Click or tap here to enter text.
Radiopharmaceuticals as CSPs						
☐	☐	☐	178	**Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in the ISO Class 8 or cleaner air environment.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements."	Click or tap here to enter text.
☐	☐	☐	179	**Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination are used by the time indicated by the manufacturers' recommendations.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see Table 1) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	180	**Technetium-99m/molybdenum-99 generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see Table 1) or cleaner air environment to permit special handling, shielding, and air flow requirements."	Click or tap here to enter text.
☐	☐	☐	181	**Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA."	Click or tap here to enter text.
☐	☐	☐	182	**Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area; a line of demarcation is established.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established."	Click or tap here to enter text.
☐	☐	☐	183	**Materials and garb exposed in patient care and treatment do not cross the line of demarcation.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area."	Click or tap here to enter text.
Allergen Extracts as CSPs						
☐	☐	☐	184	**Compounding is performed only with simple transfers using sterile ingredients and supplies.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection)."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	185	**Allergen extracts contain appropriate concentrations of preservatives.**	USP Chapter 797 - Allergen Extracts as CSPs – Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.	Click or tap here to enter text.
☐	☐	☐	186	**Before compounding, personnel appropriately wash hands with soap and water, apply alcohol-based scrub with persistent activity, don hair covers, facial hair covers, gowns, face masks and gloves.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 3. Before beginning compounding activities, personnel perform a thorough hand- cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water."	Click or tap here to enter text.
☐	☐	☐	187	**Sterile gloves are intermittently disinfected with sterile 70% IPA.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen ex-tracts as CSPs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	188	**Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 8. Ampule necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs."	Click or tap here to enter text.
☐	☐	☐	189	**Compounding manipulations are performed to minimize contact contamination of critical sites.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampules, vial stoppers)."	Click or tap here to enter text.
☐	☐	☐	190	**Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications."	Click or tap here to enter text.

Read this Page Carefully

WA Pharmacy Quality Assurance Commission

~~2022~~ 2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and~~or~~ within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

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Following your self-inspection and completion of the worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet(s), and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a commission inspector discovers an area(s) of non-compliance, they will issue an **Inspection Report with Noted Deficiencies**. The responsible manager must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non- compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not assume that you are in compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. Having all required documents and records maintained in a well- organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.
View translated versions of this statement here.

Washington State Department of Health

~~2022~~ 2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of pharmacies **must** complete and sign this self-inspection worksheet within the month of March and~~or~~ within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

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Date responsible pharmacy manager inspection was performed: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date.

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

Pharmacy: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Pharmacy License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	Are you a hospital pharmacy? **If yes, you must *only* complete the ~~2021~~ 2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet, unless you answer yes to any of the following.**
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2021~~ 2023 Non-Sterile Compounding Self-Inspection Addendum in addition to the ~~General Pharmacy~~Hospital Pharmacy and HPAC Self-Inspection Worksheet.

☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2021~~ 2023 Sterile Compounding Self-Inspection Addendum in addition to the ~~General Pharmacy~~Hospital Pharmacy and HPAC Self-Inspection Worksheet.
☐	☐	Do you have an endorsement as a Nuclear Pharmacy? **If yes, you must also complete the ~~2021~~ 2023 Nuclear Pharmacy Self-Inspection Addendum.**

Document and Record Review

~~Where are the following items located inside the pharmacy~~Please provide the location of these documents in the pharmacy (be as specific as possible, there can be many filing cabinets and binders).~~?~~ The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(e) "**The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c) "**In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Ancillary Utilization Plan Location: Click or tap here to enter text.	**WAC 246-945-410(11)(a)** "A copy of the utilization plan must be maintained in the pharmacy."

	Rule Reference
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ten business days of the change." **WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion."
Collaborative Drug Therapy Agreement(s) (CDTA) Location: Click or tap here to enter text.	**WAC 246-945-350(1)** "A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location."
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
General Requirements						
☐	☐	☐	1	**Is the current pharmacy license posted?**	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	Click or tap here to enter text.
☐	☐	☐	2	**Are the pharmacist license(s) posted and up to date?**	**RCW 18.64.140** "The current license shall be conspicuously displayed to the public in the pharmacy to which it applies."	Click or tap here to enter text.
☐	☐	☐	3	**Does the pharmacy have a DEA registration number, is it listed on page 2 of this document?**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed.	Click or tap here to enter text.
☐	☐	☐	4	**Is the responsible pharmacy manager licensed to practice pharmacy in the state of Washington?**	**WAC 246-945-310 Responsible pharmacy manager.** The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations.	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	5	**Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access?**	**WAC 246-945-410(1)** The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	6	**Is the pharmacy properly equipped?**	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.
☐	☐	☐	7	**Is the pharmacy appropriately staffed?**	**WAC 246-945-410(3)** The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.	Click or tap here to enter text.
☐	☐	☐	8	**Is the pharmacy adequately stocked?**	**WAC 246-945-410(4)** The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415.	Click or tap here to enter text.
☐	☐	☐	9	**Does the pharmacy have a designated responsible pharmacy manager?**	**WAC 246-945-410(5)** The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy.	Click or tap here to enter text.
☐	☐	☐	10	**Are the drug storage areas appropriately secure from unauthorized access?**	**WAC 246-945-410(10)** Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice.	Click or tap here to enter text.
☐	☐	☐	11	**Are refrigerators temperatures maintained between 2-8°C (36-46°F)? ** Electronic monitoring is acceptable. ****	**WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
☐	☐	☐	12	**Are freezers between -25°& -10°C (-13° & 14°F)?**	**WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
Ancillary Personnel						
☐	☐	☐	13	**Are ancillary personnel certification(s) and registration(s) up to date? *Please provide documentation of a regular staff roster with credential and expiration date.***	**WAC 246-945-205(2)** "To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020," **WAC 246-945-200(1)** "To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of chapter 246-12 WAC, Part 2."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	14	**Is the pharmacy adhering to a commission approved Ancillary Utilization Plan?**	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **WAC 246-945-410(11)** "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	15	**Do pharmacists appropriately delegate functions to ancillary personnel?**	**WAC 246-945-315** All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks. (2) When delegating a pharmacy function to a pharmacy technician: (a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and (b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320. (3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions. **WAC 246-945-317 Tech check tech.** (1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example. (2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight-hour supply of drugs	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	
☐	☐	☐	16	**Does the pharmacy have a copy of the ancillary utilization plan?**	**WAC 246-945-410(11)(a)** "A copy of the utilization plan must be maintained in the pharmacy"	Click or tap here to enter text.
☐	☐	☐	17	**Does the pharmacy utilize tech check tech?**	**WAC 246-945-317(2)** A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight-hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	Click or tap here to enter text.
Electronic Recordkeeping Requirements **Please perform appropriate audits on pages 19-20**						
☐	☐	☐	18	**Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?**	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	Click or tap here to enter text.
☐	☐	☐	19	**Are all drugs dispensed only upon a valid order?**	**WAC 246-945-410(7)** Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. **WAC 246-945-011(5)** A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. **RCW 18.64.550(1)** A chart order must be considered a prescription if it contains:(a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed;(d) Directions for use; and (e) An authorized signature:	Click or tap here to enter text.
Policies and Procedures						
☐	☐	☐	20	**Does the pharmacy have policies and procedures adequate to address pharmacy functions?**	**WAC 246-945-410(6)** The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
					related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled sub-stances. (d) Controlling access to legend drugs, including controlled sub-stances.	
☐	☐	☐	21	**Do you have a policy addressing system downtime?**	**WAC 246-945-417(4)** The pharmacy shall have policies and procedures in place for system downtime.	Click or tap here to enter text.
☐	☐	☐	22	**If providing central fill services, does the pharmacy have policies and procedures outlining off-site pharmacy services?**	**WAC 246-945-425(2)(a)** The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party;	Click or tap here to enter text.
☐	☐	☐	23	**Does the pharmacy have policies and procedures for providing emergency discharge medications to patients?**	**WAC 246-945-435(1)** The responsible pharmacy manager of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available. (2) The policies and procedures in subsection (1) of this section shall: (a) Comply with all requirements of RCW 70.41.480; (b) Ensure all prepackaged medications are affixed with a label that complies with WAC 246-945-018; (c) Require oral or electronically transmitted chart orders be verified by the practitioner in writing within seventy-two hours; (d) The medications distributed as discharge medications are stored in compliance with the laws concerning security and access; and (e) Ensure discharge medications are labeled appropriately. **RCW 70.41.480(2)(b)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW."	Click or tap here to enter text.
☐	☐	☐	24	**Does the pharmacy have policies and procedures for the use of patient own medications?**	**WAC 246-945-440** Facilities shall develop written policies and procedures for the administration of patient owned medications.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	25	**Does the pharmacy have policies and procedures for nursing student administration of medications?**	**WAC 246-945-450 (1)** Nursing students may be given access privileges to technology used to dispense medications for patient administration as provided for in this section. **WAC 246-945-450 (2)** Nursing students must be enrolled in a nursing program approved by the Washington state nursing care quality assurance commission in accordance with WAC 246-840-510. **WAC 246-945-450(3)** A facility that provides a clinical opportunity to nursing students must meet the following to grant access to technology used to dispense medications for patient administration: (a) The facility, in collaboration with the nursing program, shall provide nursing students with orientation and practice experiences that include the demonstration of competency of skills prior to using the dispensing technology; (b) Nursing programs and participating facilities shall provide adequate training for students accessing dispensing technology; (c)The nursing programs and participating facilities shall have policies and procedures for nursing students to provide safe administration of medications; and (d) The nursing program and participating facilities shall develop and have a way of reporting and resolving any nursing student medication errors, adverse events, and alleged diversion.	Click or tap here to enter text.
☐	☐	☐	26	**Does the pharmacy have required policies and procedures for drugs stored outside of the pharmacy?**	**WAC 246-945-455(1)** In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met: The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; (b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450;	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					(d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs.	
☐	☐	☐	27	**Does the pharmacy meet the requirements for return and destruction of medications?** **Does the pharmacy meet the requirements for the return and reuse of medications?**	**WAC 246-945-485** A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW. (2) A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures	Click or tap here to enter text.
Drug Distribution and Control						
☐	☐	☐	28	**Does the pharmacy possess, distribute, or dispense legend drug samples?**	**WAC 246-945-035(2)** A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples.	Click or tap here to enter text.
☐	☐	☐	29	**Are all drug containers in the hospital labeled clearly and adequately to show the drug name and strength?**	**WAC 246-945-017(1)** All licensees of the commission who dispense legend drugs to hospital inpatients shall ensure all drug containers are labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength, when applicable.	Click or tap here to enter text.
☐	☐	☐	30	**Does the pharmacy dispense investigational drugs?** ***If no, skip to question. 32****	**WAC 246-945-445(1)** The responsible pharmacy manager or their designee is responsible for the storage, distribution, and control of approved investigational drugs used in an institutional facility. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.	Click or tap here to enter text.
☐	☐	☐	31	**Are investigational drugs properly labeled and stored only for use under explicit directions from principal investigators?**	**WAC 246-945-445(2)** Under the explicit direction of the authorized principal investigator, coinvestigator(s), or per study protocol requirements, investigational drugs must be properly labeled and stored for use. An appropriate medical	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					staff committee, institution review board, or equivalent committee, shall approve the use of such drugs.	
☐	☐	☐	32	**Are all drug stock and devices in date and fit for use?**	**RCW 69.04.100** Whenever the Pharmacy Quality Assurance commission shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use. **WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
Controlled Substance Accountability						
☐	☐	☐	33	**Are procedures established for effective accountability of controlled substances?**	**WAC 246-945-040(1)** The commission adopts 21 CFR as its own. **21 CFR 1301.71** All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.	Click or tap here to enter text.
☐	☐	☐	34	**Does the pharmacy have a biennial controlled substance inventory completed within the last 2 years?**	**21 CFR 1304.11** Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. **WAC 246-945-420(2)** A facility shall conduct an inventory of controlled substances every two years.	Click or tap here to enter text.
☐	☐	☐	35	**Does the pharmacy maintain records of all receipt and distribution of controlled substances?**	**WAC 246-945-040(3)** Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
					transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	
☐	☐	☐	36	**Are records of Schedule II drugs maintained separately from all other controlled substance records?**	**WAC 246-945-040(4)** Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.	Click or tap here to enter text.
☐	☐	☐	37	**Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?**	**WAC 246-945-040(5)** Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.	Click or tap here to enter text.
☐	☐	☐	38	**Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?**	**WAC 246-945-040(6)** A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.	Click or tap here to enter text.
☐	☐	☐	39	**Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?**	**WAC 246-945-040(3)(c)** In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission.	Click or tap here to enter text.
Remote Supervision and Access in the Absence of a Pharmacist						
☐	☐	☐	40	**Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site?**	**WAC 246-945-430(1)** The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies.	Click or tap here to enter text.
☐	☐	☐	41	**Does the pharmacy have full visual surveillance of the pharmacy?**	**WAC 246-945-430(2)** The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high-quality recording for a minimum of thirty calendar days.	Click or tap here to enter text.
☐	☐	☐	42	**Is access to the pharmacy limited and monitored?**	**WAC 246-945-430(3)** Access to a pharmacy by individuals must be limited, authorized, and regularly monitored.	Click or tap here to enter text.
☐	☐	☐	43	**Does the monitoring system include visual and audio communication?**	**WAC 246-945-430(4)** A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant.	Click or tap here to enter text.
☐	☐	☐	44	**Does the responsible pharmacy manager or designee perform monthly in-person inspections of the pharmacy?**	**WAC 246-945-430(5)** The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy.	Click or tap here to enter text.
☐	☐	☐	45	**Can a pharmacist be on-site within 3 hours of an emergency?**	**WAC 246-945-430(6)** A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises.	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	46	**Does the pharmacy close in the event of a surveillance system failure?**	**WAC 246-945-430(7)** The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.	Click or tap here to enter text.
☐	☐	☐	47	**Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?**	**WAC 246-945-420(4)** A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory.	Click or tap here to enter text.
☐	☐	☐	48	**When 24-hour services are not available does the pharmacist perform retrospective drug utilization review of orders within six hours of being open?**	**WAC 246-945-510(8)(d)** A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.	Click or tap here to enter text.
Outpatient Dispensing						
If the pharmacy provides outpatient dispensing services other than emergency prepackaged medications please complete the General Pharmacy Self-Inspection form in addition to the Hospital Pharmacy Self-Inspection form.						
☐	☐	☐	49	**Does the pharmacy dispense emergency outpatient prepackaged medications?**	**RCW 70.41.480(1)** "... It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available."	Click or tap here to enter text.
☐	☐	☐	50	**Does the pharmacy maintain a list of approved medications to be prepackaged and delivered?**	**RCW 70.41.480(2)(a)** "... The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: ... (a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed."	Click or tap here to enter text.
☐	☐	☐	51	**Does the pharmacy maintain records of prepackaged medications?**	**WAC 246-945-018** Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must include a label with the following information: (1) Drug name; (2) Drug strength; (3) Expiration date in accordance with WAC 246-945-016(3);	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					(4) The manufacturer's name and lot number, if not maintained in a separate record; and (5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.	
☐	☐	☐	52	**Are there criteria for when emergency prepackaged medications can be prescribed and dispensed?**	**RCW 70.41.480(2)(c)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (c) Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;"	Click or tap here to enter text.
☐	☐	☐	53	**Does the pharmacy abide by the supply limitations?**	**RCW 70.41.480(2)(f)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (d) Establishment of a limit of no more than a forty-eight hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within forty-eight hours. In no case may the policy allow a supply exceeding ninety-six hours be dispensed;"	Click or tap here to enter text.
☐	☐	☐	54	**Are prepackaged medications labeled appropriately for outpatient dispensing?**	**WAC 246-945-016(1**) All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed." **RCW 69.41.050(1)** To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					RCW 18.64.246 To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission.	
Other Areas of Non-Compliance **The commission and its inspectors reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an inspector identifies an issue of non-compliance they will note it in the section below and it will be included on the inspection report.**						
Hospital Pharmacy Associated Clinics (HPACs)						
☐	☐	☐	1	**Are there clinics owned, operated, or under common control of the hospital listed as HPACs on the hospital pharmacy license?** ***If no, you *do not* need to answer the remaining questions.**	**WAC 246-945-233(1)** A parent hospital pharmacy may add or delete a hospital pharmacy associated clinic (HPAC) to a hospital pharmacy license at any time in compliance with WAC 246-945-230(2) (a), (b), and (d).	Click or tap here to enter text.
HPAC Responsible Manager Requirements **Rule Reference for HPAC Questions**						
WAC 246-945-233 The HPAC must designate a responsible pharmacy manager and notify the commission of changes. **Policies and procedures regarding HPACs may be incorporated into the overarching hospital pharmacy required policies and procedures.						
☐	☐	☐	2	**Are procedures established for the procurement, distribution, and maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy identified for HPACs?**	**WAC 246-945-410(6)** The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled substances. (d) Controlling access to legend drugs, including controlled substances.	Click or tap here to enter text.
☐	☐	☐	3	**Are drugs located in HPACs properly stored and secured?**	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	4		**Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?**	**WAC 246-945-040(3)(c**) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission.	Click or tap here to enter text.
Facility Standards							
☐	☐	☐	5		**Do the HPACs have sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies?**	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.
☐	☐	☐	6		**Are all medication areas in the HPAC locked and secured to prevent unauthorized access?**	**WAC 246-945-410(1)** The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.	Click or tap here to enter text.
☐	☐	☐	7		**If the hospital pharmacy dispenses patient-specific drugs to an HPAC licensed under the parent hospital pharmacy, is the prescription/order information recorded in the patients' medical record?"**	**WAC 246-945-415 Dispensing and delivery of prescription drugs (8)** A licensed hospital pharmacy dispensing appropriately labeled, patient specific drugs to a HPAC licensed under the parent hospital pharmacy may do so only pursuant to a valid prescription and prescription information is authenticated in the medical record of the patient to whom the legend drug or controlled substance will be provided according to policy and procedures of the parent hospital pharmacy~~.~~	Click or tap here to enter text.
HPAC Drug Transfer and Control							
☐	☐	☐	8		**Do labels for medications dispensed to HPAC patients include:**	**RCW 18.64.246(1)** To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission. At the prescriber's request, the name and strength of the medication need not be shown. If the prescription is for a combination medication product, the generic names of the medications combined or the trade name used by the manufacturer or distributor for the product	Click or tap here to enter text.
☐	☐	☐	8	**a**	**Name of prescriber**		Click or tap here to enter text.
☐	☐	☐	8	**b**	**Directions for use**		Click or tap here to enter text.
☐	☐	☐	8	**c**	**Brand or Generic Drug name and strength per dose**		Click or tap here to enter text.
☐	☐	☐	8	**d**	**Name of patient, and**		Click or tap here to enter text.
☐	☐	☐	8	**e**	**Date**		Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
						shall be noted on the label. The identification of the licensed pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. This section shall not apply to the dispensing of medications to in-patients in hospitals. **RCW 69.41.050(1)** To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient. **WAC 246-945-016** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	
☐	☐	☐	9	**Do parenteral and irrigation solution labels include:**		**WAC 246-945-016(2)** In addition to the requirements in subsection (1) of this section, a compounded product must meet the applicable labeling requirements of USP chapters <795>, <797>, <800>, and <825>. For compounded products, the BUD shall be equivalent to the expiration date required by RCW 18.64.246. **USP 797** Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:	Click or tap here to enter text.
☐	☐	☐	9	**a**	**Patient's name**		Click or tap here to enter text.
☐	☐	☐	9	**b**	**Name and amount of drugs added**		Click or tap here to enter text.
☐	☐	☐	9	**c**	**Beyond use date; and**		Click or tap here to enter text.
☐	☐	☐	9	**d**	**Initials of personnel who prepared solution?**		Click or tap here to enter text.

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Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
					That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.		
Records							
☐	☐	☐	10		**For *automated* patient record systems: Do patient records include all required information?**	**WAC 246-945-417(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. (3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. (4) The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual record-keeping system be maintained. (5) The pharmacy shall maintain records in accordance with WAC 246-945-020. (6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311. (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
☐	☐	☐	10	a	**Patient full name and address**		Click or tap here to enter text.
☐	☐	☐	10	b	**Serial number assigned to each new prescription**		Click or tap here to enter text.
☐	☐	☐	10	c	**Date of all instances of dispensing a drug**		Click or tap here to enter text.
☐	☐	☐	10	d	**The identification of the dispenser who filled the prescription**		Click or tap here to enter text.
☐	☐	☐	10	e	**Name, strength, dosage form, and quantity of drug dispensed**		Click or tap here to enter text.
☐	☐	☐	10	f	**Prescriber's name address, and DEA number where required.**		Click or tap here to enter text.
☐	☐	☐	10	g	**Any refill instructions by the prescriber**		Click or tap here to enter text.
☐	☐	☐	10	h	**Complete directions for use of the drug, which prohibits use of "as directed"**		Click or tap here to enter text.
☐	☐	☐	10	i	**Authorization for other than child-resistant containers, if applicable.**		Click or tap here to enter text.
☐	☐	☐	11		**Are allergies and chronic conditions identified in patient records?**	**WAC 246-945-417(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer	Click or tap here to enter text.

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Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
						information, and other information necessary to provide safe and appropriate patient care. **WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	
☐	☐	☐	12		**For *manual* patient record systems: Do patient records include all required information?**	**WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	Click or tap here to enter text.
☐	☐	☐	12	**a**	**Patient full name and address**		Click or tap here to enter text.
☐	☐	☐	12	**b**	**Serial number assigned to each new prescription**		Click or tap here to enter text.
☐	☐	☐	12	**c**	**Date of all instances of dispensing a drug**		Click or tap here to enter text.
☐	☐	☐	12	**d**	**The identification of the dispenser who filled the prescription**		Click or tap here to enter text.
☐	☐	☐	12	**e**	**Name, strength, dosage form, and quantity of drug dispensed**		Click or tap here to enter text.
☐	☐	☐	12	**f**	**Prescriber's name address, and DEA number where required.**		Click or tap here to enter text.
Drug Administration							
☐	☐	☐	13		**Is access to the drug storage area of the HPAC limited only to those WA credentialed personnel acting within their scope of practice? *Nursing students acting within their scope of practice can administer medications.***	**WAC 246-945-455(1)(c)** Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450. **WAC 246-945-317 Tech check tech. (1)** "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
					must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example. (2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	
☐	☐	☐	14	**Are all drugs in an HPAC dispensed only upon a valid order or a practitioner?**	**WAC 246-945-410(7)** Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. **WAC 246-945-011(5)** A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. **RCW 18.64.550(1)** A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature.	Click or tap here to enter text.

Read this Page Carefully

WA Pharmacy Quality Assurance Commission

~~2022~~ 2023 General Pharmacy Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and~~or~~ within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not assume that you are in compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write "corrected" and the date of correction by the appropriate question. Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

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Washington State Department of Health

All responsible pharmacy managers (or equivalent managers) of pharmacies **must** complete and sign this self-inspection worksheet within the month of March and~~or~~ within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

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Date responsible pharmacy manager inspection was performed: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date. (mm/dd/yy)

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

Pharmacy: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Pharmacy License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and ~~drug administration~~drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2021~~ 2023 Non-Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2021~~ 2023 Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Please answer the following three questions to identify additional required self-inspection forms.		
☐	☐	**Does the pharmacy fill prescriptions for residents of long-term care facilities or hospice programs? (This includes retail/community pharmacies and closed-door long-term care pharmacies, as defined in RCW 18.64.011(4).)** **If yes,** please complete the ~~2021~~ 2023 Long-Term Care Pharmacy Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Is the pharmacy licensed as a hospital pharmacy and/or have HPACs?** **If yes,** please complete the ~~2021~~ 2023 Hospital and HPAC Pharmacy Self-Inspection Addendum instead of the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy have an endorsement as a Nuclear Pharmacy?** **If yes,** please complete the ~~2021~~ 2023 Nuclear Pharmacy Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Document and Record Review

~~Where are the following items located inside the pharmacy~~Please provide the location of these documents in the pharmacy (be as specific as possible, there can be many filing cabinets and binders).~~?~~ The documentation listed below is required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.

	Rule Reference
Responsible Pharmacy Manager Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **21 CFR 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."

	Rule Reference
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(e)** "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 Years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft…."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Ancillary Utilization Plan Location: Click or tap here to enter text.	**WAC 246-945-410(11)(a)** "…A copy of the utilization plan must be maintained in the pharmacy..."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."

	Rule Reference
Collaborative Drug Therapy Agreement(s) (CDTA), if applicable Location: Click or tap here to enter text.	**WAC 246-945-350(1)** "A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location."
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1	**Is the current pharmacy license posted?**	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	Click or tap here to enter text.
☐	☐	☐	2	**Are the pharmacist license(s) posted and up to date?**	**RCW 18.64.140** "…The current license shall be conspicuously displayed to the public in the pharmacy to which it applies…"	Click or tap here to enter text.
☐	☐	☐	3	**Does the pharmacy have a DEA registration number, is it listed on page 3 of this document?**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
☐	☐	☐	4	**Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?**	**WAC 246-945-332** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	5	**Are ancillary personnel certification(s) and registration(s) up to date?** **Please provide documentation of a regular staff roster with credential and expiration date.**	**WAC 246-945-205(2)** "To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020," **WAC 246-945-200(1)** "To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of chapter 246-12 WAC, Part 2."	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	6	**Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access?**	**WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	7	**Is the facility properly equipped?**	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	8	**Is the facility appropriately staffed?**	**WAC 246-945-410(3)** "The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation."	Click or tap here to enter text.
☐	☐	☐	9	**Is the facility adequately stocked?**	**WAC 246-945-410(4)** "The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415."	Click or tap here to enter text.
☐	☐	☐	10	**Does the facility have a designated responsible pharmacy manager?**	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	11	**Does each drug dispensed and delivered to patient bear a complete and accurate label?**	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	12	**Are the drug storage areas appropriately secure from unauthorized access?**	**WAC 246-945-410 (10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	13	**Is a sign posted in view of patients informing them of generic substitution requirements?**	**RCW 69.41.160** "Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, 'Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.'"	Click or tap here to enter text.
☐	☐	☐	14	**Are refrigerators temperatures maintained between 2-8°C (36-46°F)?** ****Electronic monitoring is acceptable.****	**WAC 246-945-415(1)**" A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
☐	☐	☐	15	**Are freezers between -25° & -10°C (-13° & 14°F)?**	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
Ancillary Personnel						
☐	☐	☐	16	**Is the pharmacy adhering to a commission approved Ancillary Utilization Plan?**	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **WAC 246-945-410(11)** "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	17	**Are pharmacy assistants operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?**	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (2) 'Pharmacy assistants' may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt." **WAC 246-945-315(3)** "A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions."	Click or tap here to enter text.
☐	☐	☐	18	**Are pharmacy technicians operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?**	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (1) "Pharmacy technicians" may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt... ." **WAC 246-945-315(2)** "When delegating a pharmacy function to a pharmacy technician: (a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and (b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320."	
Recordkeeping						
☐	☐	☐	19	**An electronic recordkeeping system is required.** **Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?**	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	Click or tap here to enter text.
☐	☐	☐	20	**Does all nonsterile and sterile compounding comply with USP Chapter <825>, if applicable?**	**WAC 246-945-100** "Compounding minimum standards. **(1)** All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration…. (d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	21	**Do medications dispensed under and emergency proclamation meet all requirements?**	**WAC 246-945-332** "Continuity of care (2) For each medication dispensed under this section, a pharmacist shall: (a) Document the dispensing as a prescription, noting where the information from subsection (1)(a) of this section was obtained; (b) Inform the patient's provider and the pharmacy at which the patient obtains his or her medications of the dispensing as soon as possible following the emergency dispensing; (c) Record the prescription or patient record as an "emergency" prescription."	Click or tap here to enter text.
☐	☐	☐	22	**Is prescription adaptation in compliance with laws and rules with regard to quantity, dosage form, completion of missing information, and documentation in the patient's record?**	**WAC 246-945-335** "Prescription adaptation. Upon patient consent, a pharmacist may adapt drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted. **(1)** Change quantity. A pharmacist may change the quantity of medication prescribed if: (a) The prescribed quantity or package size is not commercially available; (b) The change in quantity is related to a change in dosage form; (c) The change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520; or (d) The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program in accordance with RCW 48.43.096. **(2)** Change dosage form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. **(3)** Complete missing information. A pharmacist may complete missing information on a prescription if there is evidence to support the change. **(4)** Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	23	**Are all drug or biologic product substitutions in compliance with the applicable laws and rules?**	**WAC 246-945-340** "Prescriptions—Drug product substitutions. **(1)** A pharmacist may substitute a drug or biologic product dispensed pursuant to a prescription if in compliance with applicable laws and rules. **(2)** A pharmacist may substitute a drug product or a biologic product when any of the following applies: (a) The substitution is permitted by RCW 69.41.120; (b) The substitution is permitted by a formulary developed by an interdisciplinary team of an institutional facility; or (c) The substitution is otherwise permitted by law." **(3)** In addition to any other applicable requirements, a pharmacist shall only substitute a drug or a biologic product pursuant to subsection (2)(b) of this section if: (a) An employee or contractor of the institutional facility prescribed the drug or biologic product to be substituted; (b) The interdisciplinary team was composed of a nonpharmacist prescriber listed in RCW 69.41.030 and a pharmacist; and (c) The formulary is readily retrievable by the pharmacist."	Click or tap here to enter text.
☐	☐	☐	24	**Are lawfully prescribed drugs and devices or a therapeutically equivalent drug or device delivered to patients in a timely manner?**	**WAC 246-945-415** "Dispensing and delivery of prescription drugs **(2)** Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances: (a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-945-410(8) or 246-945-335; (b) National or state emergencies or guidelines affecting availability, usage, or supplies of drugs or devices; (c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					certain drug compounding or storage for nuclear medicine; (d) Potentially fraudulent prescriptions; or (e) Unavailability of drug or device despite good faith compliance with WAC 246-945-410(4). **WAC 246-945-415 (3)** Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge."	
☐	☐	☐	25	**Does the pharmacy provide the patient or agent with a timely alternative, if the lawfully prescribed drug is not in stock, or the prescription cannot be filled?**	**WAC 246-945-415 (4)** "If despite good faith compliance with WAC 246-945-410(4), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (2)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include, but are not limited to: (a) Contact the prescriber to address concerns such as those identified in subsection (2)(a) of this section or to obtain authorization to provide a therapeutically equivalent product; (b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or (c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner." **WAC 246-945-415 (5)** "Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions: (a) Destroy unfilled lawful prescriptions; (b) Refuse to return unfilled lawful prescriptions; (c) Violate a patient's privacy; (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and (e) Intimidate or harass a patient."	Click or tap here to enter text.
☐	☐	☐	26	**Does the pharmacy have a secured delivery area equipped with adequate security and is this addressed in the pharmacy's policy and procedures?**	**WAC 246-945-415 (6)** "Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the drug storage area. The secured delivery area must be a part of a	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager."	
☐	☐	☐	**27**		**Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)** **** Best practice recommendation: It is recommended that these authorizations are updated annually. ****	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR, Part 1700, unless: (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant. (b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	Click or tap here to enter text.
☐	☐	☐	28		**Do all prescriptions for non-controlled legend drugs have all required elements?**	**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500."	Click or tap here to enter text.
☐	☐	☐	28	**a**	**Prescriber's Name**		Click or tap here to enter text.
☐	☐	☐	28	**b**	**Name of Patient/ Authorized entity/Animal Name and Species**		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	28	c	**Date of Issuance**		Click or tap here to enter text.
☐	☐	☐	28	d	**Drug Name, Strength, and quantity**		Click or tap here to enter text.
☐	☐	☐	28	e	**Directions for Use**		Click or tap here to enter text.
☐	☐	☐	28	f	**Number of Refills**		Click or tap here to enter text.
☐	☐	☐	28	g	**Substitution Directions**		Click or tap here to enter text.
☐	☐	☐	28	h	**Prescribers Signature**		Click or tap here to enter text.
☐	☐	☐	28	i	**If written, on Tamper-resistant Paper**		Click or tap here to enter text.
☐	☐	☐	29		**Do all prescriptions for controlled drugs have all of the required elements?**	**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 CFR, Chapter II."	Click or tap here to enter text.
☐	☐	☐	29	a	**Patient's address**		Click or tap here to enter text.
☐	☐	☐	29	b	**Dosage Form**		Click or tap here to enter text.
☐	☐	☐	29	c	**Prescriber' address**		Click or tap here to enter text.
☐	☐	☐	29	d	**Prescriber's DEA number**		Click or tap here to enter text.
☐	☐	☐	30		**Does the chart order meet requirements?**	**WAC 246-945-010 (5)** "A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II"	Click or tap here to enter text.
☐	☐	☐	31		**Do all emergency prescriptions for controlled substances meet the requirements?** **Are all emergency controlled substances prescribed orally reduced to a written or electronic prescription?**	**WAC 246-945-010 (6)** "A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency." (a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis. **WAC 246-945-010 (7)** "A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	
☐	☐	☐	32	**Are all uncontrolled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?**	**WAC 246-945-010 (8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.
☐	☐	☐	33	**Are all drugs dispensed pursuant to valid prescriptions?**	**WAC 246-945-011** "Prescription validity. **(1)** Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity. **(2)** A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					and the date of dispensing is more than twelve months after the prescription's date of issue. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075]	
☐	☐	☐	34	**Do all paper prescriptions contain two lines clearly identified for a practitioner's signature, one that denotes "dispense as written" and the other "substitution permitted"?** **This is not necessary if substitution is permitted by a prior consent authorization.**	**RCW 69.41.120 (1)** "Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization. If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	Click or tap here to enter text.
☐	☐	☐	35	**Are paper prescriptions maintained in appropriate files?**	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."	Click or tap here to enter text.
☐	☐	☐	36	**Are electronic prescriptions maintained appropriately?**	**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					a system that meets the requirements of 21 CFR Sec. 1311."	
☐	☐	☐	37	**Do the prescription records contain a complete auditable trail?**	**WAC 246-945-417(2)** "The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible."	Click or tap here to enter text.
☐	☐	☐	38	**Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?**	**WAC 246-945-417** "Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records. **(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.	Click or tap here to enter text.
☐	☐	☐	39	**Do non-controlled substance prescription transfers contain sufficient information and maintain an auditable trail?** ***See 21 CFR 1306.25 (b) for the requirements for transferring controlled substance prescriptions.**	**WAC 246-945-345** "Prescription transfers. … **(2)** Upon patient request, a prescription may be transferred within the limits of state and federal law." **(3)** Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription." **(4)** Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing." **(5)** Prescriptions must be transferred by electronic means or facsimile, except in emergent situations."	Click or tap here to enter text.
☐	☐	☐	40	**Do prescription records properly document partial fills?**	**WAC 246-945-013** "Partial filling of prescriptions. **(1)** A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that: (a) The partial fill is requested by the patient or the prescriber; (b) The partial filling is recorded in the same manner as a re-filling; (c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					prescribed; and (d) Partial fills for controlled substances listed in Schedule III through V comply with 21 CFR Sec. 1306.23. **(2)** A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.	
☐	☐	☐	41	**Does your pharmacy have shared pharmacy services or utilize a central fill?**	**WAC 246-945-425** "Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following: … **(2)** Central fill shared pharmacy services in accordance with the following conditions: (a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party; (b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and (c) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution."	Click or tap here to enter text.
☐	☐	☐	42	**Is an inventory of controlled substances conducted and maintained onsite at a minimum every two years?**	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years."	Click or tap here to enter text.
☐	☐	☐	43	**Is an inventory of controlled substances completed within 30 days of a new responsible manager**	**WAC 246-945-420(3)** "A facility shall conduct its own separate inventory of controlled substances in the following situations: (a) Within thirty days of designating a	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				or on the effective date of the addition of a substance to a schedule of controlled substances?	responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." See also 21 CFR 1304.	
☐	☐	☐	44	**If legend drugs (including controlled substances) are dispensed or delivered without a pharmacist on-site, is there a perpetual inventory?**	**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory."	Click or tap here to enter text.
☐	☐	☐	45	**If prescription drugs are dispensed or delivered without pharmacy ancillary personnel physically on-site, is there a perpetual inventory?**	**WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	Click or tap here to enter text.
☐	☐	☐	46	**Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?**	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(71)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	Click or tap here to enter text.
☐	☐	☐	47	**Does the pharmacy maintain records of all receipt and distribution of controlled substances?**	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					distributed and prescriptions records for dispensers; … (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	
☐	☐	☐	48	**Are records of Schedule II drugs maintained separately from all other controlled substance records?**	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	Click or tap here to enter text.
☐	☐	☐	49	**Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?**	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."	Click or tap here to enter text.
☐	☐	☐	50	**Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?**	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	51	**Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, and other appropriate authorities?**	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission."	Click or tap here to enter text.
☐	☐	☐	52	**Are all records maintained for a minimum of two years or for a time period otherwise required?** For example, if a Pharmacy is storing, dispensing, and delivering medications without a pharmacist-on-site, it must have adequate visual surveillance of the full pharmacy and	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
				retain a high-quality recording for a minimum of thirty calendar days.			
Professional Requirements							
Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets and binders).							
☐	☐	☐	53	**Does the pharmacy have policies and procedures in place for the following as applicable?**		**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	Click or tap here to enter text.
☐	☐	☐	53	**a**	**Purchasing Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**b**	**Ordering Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**c**	**Storing Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**d**	**Compounding Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**e**	**Delivering Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**f**	**Dispensing Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	53	**g**	**Administration Location or file pathway:**		Click or tap here to enter text.
☐	☐	☐	54	**Does the pharmacy have a policy in place if a computer system downtime occurs? Location or file pathway:**		**WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	55	**Do pharmacists perform drug utilization reviews when required?**	**WAC 246-945-001(29)** "'Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: (a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	Click or tap here to enter text.
☐	☐	☐	56	**Do pharmacists perform patient counseling?**	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.
☐	☐	☐	57	**Do pharmacists that engage in activities under a collaborative drug therapy agreement (CDTA) have an unexpired CDTA containing the minimum required elements?**	**WAC 246-945-350 "**Collaborative drug therapy agreements. **(1)** A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location. **(2)** A CDTA must include: (a) A statement identifying the practitioner authorized to prescribe and the name of each	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					pharmacist who is party to the agreement; (i) The practitioner authorized to prescribe must be in active practice; and (ii) The authority granted must be within the scope of the practitioners' current practice. (b) A statement of the type of prescriptive authority decisions which the pharmacist is authorized to make, which includes: (i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case. (ii) A general statement of the training required, procedures, decision criteria, or plan the pharmacist is to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved. (c) A statement of the activities the pharmacist is to follow in the course of exercising prescriptive authority, including: (i) Documentation of decisions made; and (ii) A plan for communication or feedback to the authorizing practitioner concerning specific decisions made. **(3)** A CDTA is only valid for two years from the date of signing. **(4)** Any modification of the written guideline or protocol shall be treated as a new CDTA."	
☐	☐	☐	58	**Is all merchandise in date?** **Including OTC medications anywhere within the store, not solely behind the counter.** ***It's advised to perform an inventory check for expired medications while filling out this self- inspection report***	**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	59	**Does the pharmacy meet the requirements for the return and reuse of medications?**	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	Click or tap here to enter text.
☐	☐	☐	60	**Does the pharmacy meet the requirements for return and destruction of medications?**	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures	Click or tap here to enter text.
☐	☐	☐	61	**Does the pharmacy possess, distribute, or dispense legend drug samples?**	**WAC 246-945-035** "Drug sample prohibitions **(1)** "Except as provided in subsection (2) of this section, a pharmacy shall not possess, distribute or dispense legend drug samples. **(2)** A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples."	Click or tap here to enter text.
☐	☐	☐	62	**Are all drugs ready to be dispensed to patients properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?**	**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "Prescriptions—Outpatient labels—Minimum requirements. **(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity. **(3)** For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors."	
☐	☐	☐	63	**Does the pharmacy have required policies and procedures for drugs stored outside of the pharmacy?**	**WAC 246-945-455(1)** "In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					from an emergency department at a registered institutional facility, the following conditions must be met: (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; (b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450; (d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs."	
~~☐~~	~~☐~~	~~☐~~	~~64~~	~~**Are components for compounding that do not have an expiration date from the manufacturer or supplier labeled with:** **The date of receipt** **Assigned a conservative expiration date, that does not exceed 3 years after the receipt** **This date should take into consideration the nature of the component, its degradation mechanism, the packaging/container, and storage conditions.**~~	~~**RCW 18.64.270(2)** "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." USP 795 Component Selection, Handling, and Storage "For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."~~	~~Click or tap here to enter text.~~
☐	☐	☐	6~~4~~5	**Are prescriptions being refilled in accordance with pharmacy laws and rules?**	**WAC 246-945-012** "Prescription refills. **(1)** A prescription for a controlled substance listed in Schedule II cannot be refilled. **(2)** A prescription for a controlled substance listed in Schedule III, IV, or V may be refilled a maximum of five times as indicated by the prescriber. The prescription will expire six months after the date of issue pursuant to WAC 246-945-011 even if there are refills remaining.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) A prescription for a noncontrolled legend drug may be refilled as indicated by the prescriber in accordance with RCW 18.64.520. There is no limit on the number of refills, but the prescription will expire after twelve months from the date of issue pursuant to WAC 246-945-011." **WAC 246-945-330** "Refilling prescriptions. **(1)** A prescription may be refilled when permitted by state and federal law and only as authorized by the prescriber. **(2)** Except as provided in subsection (1) of this section, a pharmacist may renew a prescription for a noncontrolled legend drug one time in a six-month period when an effort has been made to contact the prescriber and they are not available for authorization under the following conditions: (a) The amount dispensed is the quantity on the most recent fill or a thirty-day supply, whichever is less; (b) The refill is requested by the patient or the patients agent; (c) The patient has a chronic medical condition; (d) No changes have been made to the prescription; and (e) The pharmacist communicates the renewal to the prescriber within one business day."	
☐	☐	☐	6~~6~~	**When prescriptions are delivered, does the pharmacy have appropriate measures in place to ensure product integrity?**	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
Remote Supervision and Access in the Absence of a Pharmacist						
☐	☐	☐	6~~7~~	**Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site?** ****If you answered "No" to question 67, mark questions 68-74 N/A.**	**WAC 246-945-430(1)** "The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies."	Click or tap here to enter text.
☐	☐	☐	6~~8~~	**Does the pharmacy have full visual surveillance of the pharmacy?**	**WAC 246-945-430(2)** "The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high quality recording for a minimum of thirty calendar days."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	6~~89~~	**Is access to the pharmacy limited and monitored?**	**WAC 246-945-430(3)** "Access to a pharmacy by individuals must be limited, authorized, and regularly monitored."	Click or tap here to enter text.
☐	☐	☐	~~706~~ 9	**Does the monitoring system include visual and audio communication?**	**WAC 246-945-430(4)** "A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant."	Click or tap here to enter text.
☐	☐	☐	70~~1~~	**Does the responsible pharmacy manager or designee perform monthly in-person inspections of the pharmacy?**	**WAC 246-945-430(5)** "The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	71~~2~~	**Can a pharmacist be on-site within 3 hours of an emergency?**	**WAC 246-945-430(6)** "A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises."	Click or tap here to enter text.
☐	☐	☐	72~~3~~	**Does the pharmacy close in the event of a surveillance system failure?**	**WAC 246-945-430(7)** "The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations."	Click or tap here to enter text.
☐	☐	☐	73~~4~~	**Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?**	**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory." **WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	Click or tap here to enter text.

Read this page carefully

WA Pharmacy Quality Assurance Commission
Pharmacy Self-Inspection Worksheet
~~2022~~ 2023 Long-Term Care Pharmacy Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this self-inspection worksheet addendum within the month of March ~~or~~ and within 30 days of becoming responsible manager (as required by WAC 246-945-005(4)) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

The primary objective of this worksheet addendum, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet addendum also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether your pharmacy is compliant with many of the rules and regulations. If any deficiencies have been corrected, please write corrected and the date of correction by the appropriate question.

Date responsible pharmacy manager inspection was performed: Click or tap to enter a date.

Signature of responsible manager: Click or tap here to enter text. _____

Responsible Pharmacy Manager E-mail: Click or tap here to enter text. _____

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Definitions - Below are terms used in this document you should keep in mind as regulations around pharmaceutical services have different standards based on the type of facility your pharmacy services.
RCW 18.64.011(4) "'Closed door long-term care pharmacy' means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public."
RCW 18.64.011(16) "'Hospice program' means a hospice program certified or paid by Medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.
RCW 18.64.011(20) "'Long-term care facility' means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW."
RCW 18.51.010(3) "Nursing home" means any home, place or institution which operates or maintains facilities providing convalescent or chronic care, or both, for a period in excess of twenty-four consecutive hours for three or more patients not related by blood or marriage to the operator, who by reason of illness or infirmity, are unable properly to care for themselves. Convalescent and chronic care may include but not be limited to any or all procedures commonly employed in waiting on the sick, such as administration of medicines, preparation of special diets, giving of bedside nursing care, application of dressings and bandages, and carrying out of treatment prescribed by a duly licensed practitioner of the healing arts. It may also include care of mentally incompetent persons. It may also include community-based care. Nothing in this definition shall be construed to include general hospitals or other places which provide care and treatment for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both. Nothing in this definition shall be construed to include any *assisted living facility, guest home, hotel or related institution which is held forth to the public as providing, and which is operated to give only board, room and laundry to persons not in need of medical or nursing treatment or supervision except in the case of temporary acute illness. The mere designation by the operator of any place or institution as a hospital, sanitarium, or any other similar name, which does not provide care for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both, shall not exclude such place or institution from the provisions of this chapter: PROVIDED, That any nursing home providing psychiatric treatment shall, with respect to patients receiving such treatment, comply with the provisions of RCW 71.12.560 and 71.12.570.
RCW 18.20.020(2) "Assisted living facility" means any home or other institution, however named, which is advertised, announced, or maintained for the express or implied purpose of providing housing, basic services, and assuming general responsibility for the safety and well-being of the residents, and may also provide domiciliary care, consistent with chapter 142, Laws of 2004, to seven or more residents after July 1, 2000. However, an assisted living facility that is licensed for three to six residents prior to or on July 1, 2000, may maintain its assisted living facility license as long as it is continually licensed as an assisted living facility. "Assisted living facility" shall not include facilities certified as group training homes pursuant to RCW 71A.22.040, nor any home, institution or section thereof which is otherwise licensed and regulated under the provisions of state law providing specifically for the licensing and regulation of such home, institution or section thereof. Nor shall it include any independent senior housing, independent living units in continuing care retirement communities, or other similar living situations including those subsidized by the department of housing and urban development.
RCW 70.128.010(1) "Adult family home" means a residential home in which a person or persons provide personal care, special care, room, and board to more than one but not more than six adults who are not related by blood or marriage to the person or persons providing the services.

Document and Record Review

Please provide the location of these documents in the facility ~~Where are the following items located inside the pharmacy~~ (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Ancillary Utilization Plan **Location:** Click or tap here to enter text. **If you are a **closed door long-term care pharmacy** and pharmacy technicians are performing administrative tasks, your plan should address that.**	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel." **RCW 18.64.580** "For the purpose of such standards, a pharmacy technician licensed under chapter 18.64A RCW may not be considered to be practicing as a pharmacy technician while performing administrative tasks not associated with immediate dispensing of drugs that may lawfully be performed by a registered pharmacy assistant. Administrative tasks not associated with immediate dispensing of drugs include but are not necessarily limited to medical records maintenance, billing, prepackaging unit dose drugs, inventory control, delivery, and processing returned drugs."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
General Requirements						
☐	☐	☐	1	**Do you fill medications for residents of a long-term care facility or hospice program?**	**RCW 18.64.550** "(1) A chart order must be considered a prescription if it contains…"	Click or tap here to enter text.
☐	☐	☐	2	**Does the pharmacy supply medications to long-term care facilities or hospice programs?**		Click or tap here to enter text.
☐	☐	☐	3	**Are medications filled from:**		
				a. **Prescriptions?** See general inspection for prescription requirements.		Click or tap here to enter text.
				b. **Chart orders?** See question 4 or chart order requirements.		Click or tap here to enter text.
☐	☐	☐	4	**Do the chart orders include:** **Patient's full name** **Date order was issued** **Name, strength, and dosage form of drug** **Directions for use; and** **Authorized Signature**	**RCW 18.64.550(1)** A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature; (i) For written orders, the order must contain the	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
				Quantity is not required, and authorized signature may be the practitioner's agent, if order is for a non-controlled legend drug or over-the counter medication.	prescribing practitioner's signature or the signature of the practitioner's authorized agent, including the name of the prescribing practitioner; or (ii) For electronic or digital orders, the order must contain the prescribing practitioner's electronic or digital signature, or the electronic or digital signature of the practitioner's authorized agent, including the name of the prescribing practitioner.	
Emergency Drug & Supplemental Drug Kits						
☐	☐	☐	5	**Do you supply medications to a nursing home to stock an emergency drug kit and/or a supplemental dose kit?**	**RCW 18.64.560(1) and (2)** "A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source. (2) In addition to or in connection with the emergency kit authorized under subsection (1) of this section, a nursing home that employs a unit dose drug distribution system may maintain a supplemental dose kit for supplemental nonemergency drug therapy. Supplemental dose kits must be secured in a locked room, container, or device to prevent unauthorized access, and to ensure the proper environment for preservation of the drugs. Administration of drugs from a supplemental dose kit must be under a valid prescription or chart order."	Click or tap here to enter text.
☐	☐	☐	6	**Do you supply medications to a hospice program to stock an emergency drug kit?**	**RCW 18.64.560(1)** "A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source."	
☐	☐	☐	7	**Are medications administered to a resident from an emergency drug kit or supplemental dose kit originate from a valid prescription or chart order?**	**RCW.18.64.560 (1) and (2**) "…. Administration of drugs from a supplemental dose kit must be under a valid prescription or chart order."	Click or tap here to enter text.
☐	☐	☐	8	**Are medications in the emergency drug kit or supplemental dose kit selected by a pharmaceutical services committee that meets minimum requirements?**	**RCW 18.64.560(3)** The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program using an emergency kit or supplemental dose kit and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee that includes a pharmacist licensed under this chapter, a physician licensed under chapter 18.71 RCW, an osteopathic physician licensed under chap 18.57 RCW, or an advanced registered nurse practitioner licensed under chapter 18.79 RCW, and appropriate clinical or administrative personnel of the nursing home or hospice program as set forth in rules adopted by the pharmacy quality assurance commission.	Click or tap here to enter text.
Policies & Procedures						
☐	☐	☐	9	**Does the pharmacy have a copy of policy and procedure(s) developed by the pharmacy service committee that provides for proper storage and security of drugs provided by the pharmacy?**	**RCW 18.64.560(3) "**The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee…"	Click or tap here to enter text.
Prepackaged Medication Label						
☐	☐	☐	10	**Does the label for ~~an~~ a unit dose prepackaged medication contain the following information:** **a** **Drug name** **b** **Drug strength** **c** **Expiration date**	**WAC 246-945-018** Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must include a label with the following information: (1) Drug name;	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				d	**Manufacturer's name and lot number**	(2) Drug strength; (3) Expiration date in accordance with WAC 246-945-016(3); (4) The manufacturer's name and lot number, if not maintained in a separate record; and (5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.	
				e	**Pharmacist or provider identity**		
Return and Reuse of Medication							
☐	☐	☐	11		**Do you repackage and dispense unused drugs only when returned by a long-term care facility or hospice program in per-use, blister packaging, whether in unit dose or modified unit dose form, except as prohibited by federal law?**	**RCW 18.64.570(4)** "A pharmacy may repackage and dispense unused drugs returned by a long-term care facility or hospice program to the pharmacy in per-use, blister packaging, whether in unit dose or modified unit dose form, except as prohibited by federal law."	Click or tap here to enter text.
☐	☐	☐	12		**If unused drugs are returned to the pharmacy for reuse can the product integrity be assured by the pharmacy or do the returned drugs qualify for reuse under the provisions of chapter 69.70 RCW?**	**WAC 246-945-485(1)(a)** (1) A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured; and (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	Click or tap here to enter text.
Shared Pharmacy Services							
☐	☐	☐	13		**If pharmacy services are provided off-site, does the pharmacy or pharmacist comply with RCW 18.64.570**	**WAC 246-945-425 Shared pharmacy services.** Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following: (1) Long term care shared pharmacy services in accordance with RCW 18.64.570.	Click or tap here to enter text.
☐	☐	☐	14		**Are prescriptions outsourced for a long-term care facility or hospice program?**	**RCW 18.64.570(3)** "Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet the immediate needs of residents of the long-term	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
				Does the pharmacy outsource to other pharmacies serving long term care or hospice programs? Answer question 19 (outsourcing pharmacy). **Does the pharmacy supply medications for other pharmacies serving long term care or hospice programs? Answer question 20 (supplying pharmacy).**	care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis……"	
☐	☐	☐	15	***Outsourcing Pharmacy*: Is a copy of the prescription or chart order provided to the supplying pharmacy?**	**RCW 18.64.570(2)** "A pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program to another pharmacy if the outsourcing pharmacy: **(a)** Obtains approval from the long-term care facility or hospice program to outsource shared pharmacy services for the facility's or program's residents or patients; and **(b)** Provides a copy of the prescription or order to the pharmacy providing the shared pharmacy services."	Click or tap here to enter text.
☐	☐	☐	16	***Supplying Pharmacy*: Is a copy of the prescription or drug order and dispensing record between the outsourcing pharmacy and the supplying pharmacy maintained?**	**RCW 18.64.570(3)** "Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet the immediate needs of residents of the long-term care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis. Where a pharmacy uses shared pharmacy services to have a second pharmacy provide a first dose or partial fill of a prescription or drug order to meet a patient's or resident's immediate needs, the second supplying pharmacy may dispense the first dose or partially filled prescription on a satellite basis without the outsourcing pharmacy being required to fully transfer the prescription to the supplying pharmacy. The supplying pharmacy must retain a copy of the prescription or order on file, a copy of the dispensing record or fill, and must notify the outsourcing pharmacy of the service and quantity provided."	Click or tap here to enter text.

Washington State Department of Health

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WA Pharmacy Quality Assurance Commission

Pharmacy Self-Inspection Worksheet

~~2022~~ 2023 USP <795> – Nonsterile Compounding Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March and~~or~~ within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy or Hospital Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

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The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace U.S. Pharmacopeia (USP) <795> Pharmaceutical Compounding – Sterile Preparations. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write "corrected" and the date of correction by the appropriate question.

For additional guidance on the self-inspection addendum, please see Guidance Document #61 – United States Pharmacopeia General Chapter <795> – Nonsterile Compounding – Information.

Date responsible manager/change of responsible manager inspection was performed: Click or tap to enter a date.

Signature of responsible pharmacy manager: Click or tap here to enter text.

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov. View translated versions of this statement here.

General Rule Reference - Applies to all questions through worksheet.
RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Training & Training Procedures						
☐	☐	☐	1	Are all licensed pharmacy personnel involved in compounding properly trained for the type of compounding they perform? ***USP recommends annual evaluations of personnel training.***	**USP <795> - Categories of Compounding** - "Compounders shall acquire and maintain knowledge and skills in all areas (e.g. dosage, form, patient population, and medical specialty) for which they compound." **USP <795> - Training** - "All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	2	Do training procedures require all pharmacy personnel who compound to read and be familiar with <USP 795>?	**USP <795> -** "Steps in the training procedure include the following: • All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the USP Pharmacists' Pharmacopeia and other relevant publications, including how to read and interpret MSDSs."	Click or tap here to enter text.
☐	☐	☐	3	Do training procedures require **all pharmacy personnel who compound** to read and be familiar with your pharmacy's procedures related to compounding?	**USP <795> -** "Steps in the training procedure include the following: • All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing."	Click or tap here to enter text.
☐	☐	☐	4	Do training procedures include hazardous drug training if hazardous drugs are handled in the pharmacy?	**USP <795> -** "Steps in the training procedure include the following: • All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs."	Click or tap here to enter text.

Compliant Yes	No	N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	5	Do training procedures require all training activities to be documented by the responsible manager?		**USP <795> -** "Steps in the training procedure include the following: • All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employees may have concerning compounding procedures."	Click or tap here to enter text.
			6	Do training procedures include the following?		**USP <795> - Training -** "Steps in the training procedure include the following:	Click or tap here to enter text.
☐	☐	☐	6	a	Demonstration and observation of proper procedures and knowledge of procedures.	**USP <795> - Training -** "The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder. • When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	6	b	Requiring signatures on training documentation.	**USP <795> - Training -** "When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	6	c	Pharmacist monitoring of employee's work.	**USP <795> - Training "**Steps in the training procedure include the following: • The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed." ***Compounder in this reference means a pharmacist.***	Click or tap here to enter text.

Compliant Yes	No	N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	6	d	Pharmacist responsibility for final preparation.	**USP <795> - Training** "Steps in the training procedure include the following: • The compounder is solely responsible for the finished preparation." ***Compounder in this reference means a pharmacist.***	Click or tap here to enter text.
Compounding Process							
In the Rule References for Questions 7 -18 "compounder" can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.							
☐	☐	☐	7		Do employees engaged in compounding check to ensure that the dose, safety, and intended use of the product or preparation has been evaluated for suitability?	**USP <795> -** The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **1.** The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of: • the chemical and physical properties of the components • dosage form • therapeutic appropriateness and route of administration, including local and systemic biological disposition • legal limitations, if any.	Click or tap here to enter text.
☐	☐	☐	8		Do employees engaged in compounding check ingredients to be used in the preparation have their expected identity, quality, and purity?	**USP <795> - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov) "	Click or tap here to enter text.
☐	☐	☐	9		Do employees engaged in compounding verify that formulations intended for human use or food producing animals are checked to ensure they are not on a list of prohibited items for use in these formulations?	**USP <795> - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used."	Click or tap here to enter text.
☐	☐	☐	10		Is the compounding area appropriately clean and sanitized?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **4.** Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section Compounding Facilities)."	Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	11	Are compounds prepared one at a time in a specific or dedicated workspace?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **5.** Only one preparation is compounded at one time in a specific workspace."	Click or tap here to enter text.
☐	☐	☐	12	Is compounding equipment inspected for cleanliness and proper functioning?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **6.** Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used."	Click or tap here to enter text.
☐	☐	☐	13	Are appropriate BUDs assigned to finished preparations?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **7.** A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD."	Click or tap here to enter text.
☐	☐	☐	14	Do employees engaged in compounding properly wash hands and wear the proper PPE based on the type of compounding performed?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **8.** Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination."	Click or tap here to enter text.
☐	☐	☐	15	Are critical processes verified by a pharmacist during compounding to ensure expected qualities of the finished preparation?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **10.** Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation."	Click or tap here to enter text.
☐	☐	☐	16	Is the final preparation assessed by a pharmacist using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **11.** The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record."	Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	17	Is the final preparation properly labeled?	**USP <795> -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **13.** The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information." ***See RCW 18.64.246***	Click or tap here to enter text.
Compounding Facilities						
☐	☐	☐	18	Is there adequate space in the compounding facility that is also designated specifically for compounding to occur?	**USP <795> -** "Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions."	Click or tap here to enter text.
☐	☐	☐	19	Do compounding facilities provide for placement of equipment and materials to avoid mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and cross-contamination?	**USP <795>** - "This space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination."	Click or tap here to enter text.
☐	☐	☐	20	Are areas for nonsterile compounding and sterile compounding separate from each other?	**USP <795>** - "Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area."	Click or tap here to enter text.
☐	☐	☐	21	Is purified water used in compounding of nonsterile preparations?	**USP <795> -** "Purified Water (see Purified Water monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water."	Click or tap here to enter text.
☐	☐	☐	22	Are adequate hand and equipment washing facilities easily accessible to the compounding area?	**USP <795> -** "Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels."	Click or tap here to enter text.
☐	☐	☐	23	Are all your compounding areas kept clean, and in good repair?	**USP <795> -** "The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair."	Click or tap here to enter text.
☐	☐	☐	24	Is waste handled in accordance with local, state, and federal guidelines?	**USP <795> -** "Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines."	Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	25	Are heating, ventilation, and air conditioning systems controlled to avoid decomposition and contamination of chemicals?	**USP <795> -** "Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity; and the manufacturers' labeled storage conditions)."	Click or tap here to enter text.
☐	☐	☐	26	Are all compounding components, equipment, and containers stored in accordance with the manufacturer or other specified conditions, off of the floor?	**USP <795> -** "All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area."	Click or tap here to enter text.
☐	☐	☐	27	Are hazardous drugs stored, prepared, and handled by trained personnel under conditions that protect all personnel?	**USP <795> -** "Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel."	Click or tap here to enter text.
☐	☐	☐	28	Does disposal of hazardous drugs comply with all applicable federal and state regulations?	**USP <795> -** "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	Click or tap here to enter text.
☐	☐	☐	29	Are all personnel who perform routine custodial waste removal and cleaning in hazardous drug preparation areas trained in appropriate procedure to protect themselves and prevent contamination?	**USP <795>** - "All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	Click or tap here to enter text.
Compounding Equipment						
☐	☐	☐	30	Is equipment appropriate for use in compounding?	**USP <795> -** "The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity…. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations."	Click or tap here to enter text.
☐	☐	☐	31	Is all equipment stored to protect it from contamination and located to facilitate use, maintenance and cleaning?	**USP <795> -** "Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning."	Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	32	Are automated, mechanical, electronic, or other technology used in compounding routinely tested, inspected, and calibrate to ensure proper performance?	**USP <795> -** "Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance."	Click or tap here to enter text.
☐	☐	☐	33	Is equipment checked by employees engaged in compounding to determine its suitability for use in compounding?	**USP <795> -** "Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	34	Is equipment used during compounding cleaned after use?	**USP <795>** - "After use, the equipment shall be appropriately cleaned."	Click or tap here to enter text.
☐	☐	☐	35	If the same equipment is being used for all drug products, are there procedures in place that allow meticulous cleaning of equipment before use with other drugs?	**USP <795> -** "… when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs."	Click or tap here to enter text.
Component Selection, Handling, and Storage						
☐	☐	☐	36	Are components used in compounding manufactured by FDA-registered facilities?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** Compounders shall first attempt to use components manufactured in an FDA-registered facility." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	37	If components are not available from FDA-registered facilities, is professional judgment used when selecting components and to establish purity and safety by reasonable means?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	38		Do ingredients used in preparations meet the requirements of compendial monographs for those ingredients? *See point 4 in rule reference column to the right, for when compendial quality components are not obtainable.*	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **3.** Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled USP or NF as appropriate. **4.** When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used."	Click or tap here to enter text.
☐	☐	☐	39		When components are transferred from an original container to a different container, is that container identified with:	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **5.** For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date **(a)** when the material is stored in its original container under conditions to avoid decom-position of the chemicals ... **(b)** when there is minimal exposure of the remaining material each time material is withdrawn from the container, and **(c)** when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container."	Click or tap here to enter text.
☐	☐	☐	39	a	Component Name		Click or tap here to enter text.
☐	☐	☐	39	b	Original Supplier		Click or tap here to enter text.
☐	☐	☐	39	c	Lot or Control Number		Click or tap here to enter text.
☐	☐	☐	39	d	Transfer Date, and		Click or tap here to enter text.
☐	☐	☐	39	e	Expiration Date		Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	40	When components do not have an expiration date assigned by the manufacturer/supplier, is the container labeled with date of receipt, and assigned a conservative expiration date that does not exceed 3 years from receipt?	**USP <795> - "**The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **6.** For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the Component (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	Click or tap here to enter text.
☐	☐	☐	41	Are manufactured drug products used by your pharmacy as the source of active ingredient manufactured by FDA-registered facilities and is appropriately labeled with a batch control number and expiration date?	**USP <795> -** The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date.	Click or tap here to enter text.
☐	☐	☐	42	Does the compounder consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components."	Click or tap here to enter text.
☐	☐	☐	43	Do ingredients used for dietary or nutritional supplements meet USP, FCC or NF standards?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **8.** If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet USP, FCC, or NF standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures."	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
☐	☐	☐	44	Does your pharmacy receive written assurance from suppliers that components derived from ruminant animals are in compliance with federal laws?	**USP <795> -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **9.** When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials."	Click or tap here to enter text.
☐	☐	☐	45	Are components used in compounding stored properly per manufacturer?	**USP <795> -** "All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean area, and under appropriate temperature and humidity conditions."	Click or tap here to enter text.
☐	☐	☐	46	Are components used in compounding stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first?	**USP <795> -** "All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	Click or tap here to enter text.
Stability Criteria and Beyond-Use Dating						
☐	☐	☐	47	Is the BUD determined from when the preparation is compounded?	**USP <795> -** "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded."	Click or tap here to enter text.
☐	☐	☐	48	When assigning a BUD, are drug specific and general stability documents and literature consulted?	**USP <795> -** "When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available …"	Click or tap here to enter text.
☐	☐	☐	49	When a manufactured product is used as the source of the API for a nonsterile compounded preparation, does the compounder refer to the manufacturer, literature and stability factors to assign a beyond use date?	**USP <795> -** "When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. The compounder shall refer to and consider the following: **1.** Manufacturer for stability information **2.** literature for applicable information on stability, compatibility, and degradation of ingredients **3.** stability factors in USP <1191> All stability data shall be carefully interpreted in relation to the actual compounded formulation."	Click or tap here to enter text.
☐	☐	☐	50	Are preparations, at all steps in compounding, dispensing, and storage, observed for signs of instability and deterioration?	**USP <795> -** "At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability."	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
Packaging and Drug Preparation Containers						
☐	☐	☐	51	Do containers and closures used for packaging preparations meet USP requirements?	**USP <795> -** "The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet USP requirements (see <659>; Containers—Glass <660>; Plastic Packaging Systems and their Materials of Construction <661>; Plastic Materials of Construction <661.1>; Plastic Packaging Systems for Pharmaceutical Use <661.2>; Containers—Performance Testing <671>; <1136>); and when available, compounding monographs Container suppliers shall supply, upon request, verification of USP container compliance." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	Click or tap here to enter text.
☐	☐	☐	52	Are the containers and closures used for packaging preparations made of suitable clean material?	**USP <795> -** "The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation."	Click or tap here to enter text.
☐	☐	☐	53	Are the containers and closures used for packaging preparations stored appropriately off the floor in way to prevents contamination and rotated?	**USP <795> -** "The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	Click or tap here to enter text.
☐	☐	☐	54	Are the containers and container closures stored in such a way as to permit inspection and cleaning of the storage area?	**USP <795> -** "The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area."	Click or tap here to enter text.
Compounding Documentation						
☐	☐	☐	55	Does the compounder compound preparation in any other way than the manufacture's labeling instructions?	**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
			56	If yes to Question 55, does the **Master Formula** contain?		**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	Click or tap here to enter text.
☐	☐	☐	56	a	Official or assigned name, strength, and dosage form of the preparation?	**USP <795> -** "this record shall include: Official or assigned name, strength, and dosage form of the preparation."	Click or tap here to enter text.
☐	☐	☐	56	b	Calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients?	**USP <795> -** "this record shall include; calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients."	Click or tap here to enter text.
☐	☐	☐	56	c	Description of all ingredients and their quantities?	**USP <795> -** "this record shall include: description of all ingredients and their quantities."	Click or tap here to enter text.
☐	☐	☐	56	d	Compatibility and stability information, including references when available?	**USP <795> -** "this record shall include: compatibility and stability information, including references when available."	Click or tap here to enter text.
☐	☐	☐	56	e	Equipment needed to prepare the preparation, when appropriate?	**USP <795> -** "this record shall include: equipment needed to prepare the preparation, when appropriate."	Click or tap here to enter text.
☐	☐	☐	56	f	Mixing instructions?	**USP <795> -** "this record shall include: Mixing instructions that should include order of mixing, mixing temperatures and environmental controls, duration of mixing, other factors pertinent to the replication of the preparation as compounded.	Click or tap here to enter text.
☐	☐	☐	56	g	Container used in dispensing?	**USP <795> -** "this record shall include: container used in dispensing."	Click or tap here to enter text.
☐	☐	☐	56	h	Packaging and storage requirements?	**USP <795> -** "this record shall include: packaging and storage requirements."	Click or tap here to enter text.
☐	☐	☐	56	i	A description of the final preparation?	**USP <795> -** "this record shall include: description of the final preparation."	Click or tap here to enter text.
☐	☐	☐	56	j	Quality control procedures and expected results?	**USP <795> -** "this record shall include: Quality control procedures and expected results."	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
			57	If yes to Question 55, does the **Compounding Formula** contain?		**USP <795> - "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	Click or tap here to enter text.
☐	☐	☐	57	a	Official or assigned name, strength, and dosage of the preparation?	**USP <795> -** "this record shall include: official or assigned name, strength, and dosage of the preparation."	Click or tap here to enter text.
☐	☐	☐	57	b	Master formula Record reference for the preparation?	**USP <795> -** "this record shall include: Master formula Record reference for the preparation."	Click or tap here to enter text.
☐	☐	☐	57	c	Names and quantities of all components?	**USP <795> -** "this record shall include: names and quantities of all components."	Click or tap here to enter text.
☐	☐	☐	57	d	Sources, lot numbers, and expiration dates of all components?	**USP <795> -** "this record shall include: sources, lot numbers, and expiration dates of all components."	Click or tap here to enter text.
☐	☐	☐	57	e	Total quantity compounded?	**USP <795> -** "this record shall include: total quantity compounded."	Click or tap here to enter text.
☐	☐	☐	57	f	Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation?	**USP <795> -** "this record shall include: Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation."	Click or tap here to enter text.
☐	☐	☐	57	g	Date of preparation?	**USP <795> -** "this record shall include: date of preparation."	Click or tap here to enter text.
☐	☐	☐	57	h	Control or prescription number?	**USP <795> -** "this record shall include: assigned control or prescription number."	Click or tap here to enter text.
☐	☐	☐	57	i	Assigned BUD?	**USP <795> -** "this record shall include: assigned BUD.	Click or tap here to enter text.
☐	☐	☐	57	j	Duplicate label described in the Master Formulation Record?	**USP <795> -** "this record shall include: duplicate label as described in the Master Formulation Record."	Click or tap here to enter text.
☐	☐	☐	57	k	Description of final preparation?	**USP <795> -** "this record shall include: description of the final preparation."	Click or tap here to enter text.
☐	☐	☐	57	l	Results of the quality control procedures?	**USP <795> -** "this record shall include: results of the quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)"	Click or tap here to enter text.

Compliant Yes	No	N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	57	m	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver?	**USP <795> -** "this record shall include: documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver."	Click or tap here to enter text.
☐	☐	☐	58		Are Safety Data Sheets readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility?	**USP <795> -** "Material Safety Data Sheets (MSDSs) shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises."	Click or tap here to enter text.
Quality Control							
☐	☐	☐	59		Do pharmacists supervising compounding activities perform a final check that reviews each procedure used in the compounding process and observe the finished preparation to ensure it appears as expected?	**USP <795> -** "As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient." ***Compounder in this reference means a pharmacist.***	Click or tap here to enter text.
☐	☐	☐	60		Are controls in place to ensure compounding accuracy?	**USP <795> - Compounding Controls** "**1.** The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented. **2.** The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process. **3.** The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity. **4.** Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	Click or tap here to enter text.

Compliant Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
Compounding for Animal Patients						
☐	☐	☐	61	Do you compound products for animal patients? ***If no, you do not need to answer the questions below***		Click or tap here to enter text.
☐	☐	☐	62	Is the intended use by the animal determined prior to compounding preparation?	**USP <795> -** "Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient."	Click or tap here to enter text.
☐	☐	☐	63	Do employees engaged in compounding for animals have knowledge of drug regulation and disposition for animal patients?	**USP <795> -** "All compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	Click or tap here to enter text.
☐	☐	☐	64	Do labels include withdrawal time lengths for animals that are food-producing?	**USP <795> -** "Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species."	Click or tap here to enter text.
☐	☐	☐	65	Do your pharmacists have knowledge of individual species' limitations in physiology and metabolic capacities? What are your resources?	**USP <795> -** "The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations."	Click or tap here to enter text.

Read this Page Carefully

Pharmacy Quality Assurance Commission
~~2022~~ 2023 Manufacturer Self-Inspection Worksheet

Attention: Facility Manager (Equivalent Manager or Responsible Pharmacy Manager)

Manufacturers are responsible for ensuring compliance with all applicable state and federal laws. Failure to complete this annual worksheet within the month of March and~~or~~ within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

Please note: This Manufacturer Self-Inspection Worksheet is only applicable to those entities subject to 21CFR 211.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a Manufacturer's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The manufacturer must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not **assume** compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the designated person to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.
All manufacturers MUST complete and sign this self-inspection worksheet within the month of March. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office**.

Style Definition: self-insp sections

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Date Manufacturer Self-Inspection was performed: Click or tap to enter a date.

Change in Responsible/Equivalent Manager and effective date of change: Click or tap here to enter text. DATE: Click or tap to enter a date. (mm/dd/yy)

Print name of person completing the Self-Inspection Worksheet: Click or tap here to enter text.

Signature of person completing the Self-Inspection Worksheet: Click or tap here to enter text.

Contact Person E-mail: Click or tap here to enter text. Manufacturer: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Fax: Click or tap here to enter text.

Address: Click or tap here to enter text.

DEA #: Click or tap here to enter text. Manufacturer License #: Click or tap here to enter text.

Endorsements: ☐ Controlled Substances

Document and Record Review

~~Where are the following items located inside the manufacturer~~Please provide the location of these documents in this facility (be as specific as possible, there can be many filing cabinets and binders~~)?).~~ The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.

	Rule Reference
Manufacturer Self-Inspection Worksheet for last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."

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	Rule Reference
Manufacturer License **Location:** Click or tap here to enter text.	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."
DEA Registration **Location:** Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory **Location:** Click or tap here to enter text.	**WAC 246-945-420**(2) "A facility shall conduct an inventory of controlled substances every two years." **21 CFR 1304.04(h)** "(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances **Location:** Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Schedule II Invoices for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."

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Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(b)** "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." **21 CFR 1305.13(d)** "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." **21 CFR 1305.13(e) "**The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 CFR 1305.22(g) "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106 and DEA Form 41) for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Quality and Control **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.22(d)** "The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed."
Sanitation **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 C.F.R 211.56** "(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed. (c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall

	Rule Reference
	be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135)."
Cleaning and Maintenance **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 C.F.R 211.67(b)** "Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following: (1) Assignment of responsibility for cleaning and maintaining equipment; (2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; (3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance; (4) Removal or obliteration of previous batch identification; (5) Protection of clean equipment from contamination prior to use; (6) Inspection of equipment for cleanliness immediately before use."
Control of components and drug product containers and closures: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.80 (a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed."
Drug product containers and closures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.94(d)** "Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures."
Written procedures; deviations **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.100(a)** "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit."
Sampling and testing of in-process materials and drug products **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.110(a)** "To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate: (1) Tablet or capsule weight variation; (2) Disintegration time; (3) Adequacy of mixing to assure uniformity and homogeneity;

	Rule Reference
	(4) Dissolution time and rate; (5) Clarity, completeness, or pH of solutions. (6) Bioburden testing."
Control of microbiological contamination **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.113(a)** "Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed. (b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes."
Reprocessing **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.115(a)** "Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics."
Materials examination and usage criteria **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.122(a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed."
Labeling issuance **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.125(f)** "Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed."

	Rule Reference
Packaging and labeling operations **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.130** "There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: (a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products. (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container. (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. (d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record. (e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records."
Warehousing procedures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.142** "Written procedures describing the warehousing of drug products shall be established and followed. They shall include: (a) Quarantine of drug products before release by the quality control unit. (b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected."
Distribution procedures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.150** "Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary."
Laboratory control: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.160(b)(4)** "The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."
Testing and release for distribution **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.165(c)** "Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed."

	Rule Reference
Stability testing **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.166(a)** "There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include: (1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."
Special testing requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.167** "(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed. (b)For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed. (c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."
Records and reports: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.180** "…(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for: (1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch. (2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under §211.192 for each drug product. (f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration."
Master production and control records **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."
Complaint files	**21 CFR 211.198(a)** "Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control

	Rule Reference
Title: Click or tap here to enter text. **Location:** Click or tap here to enter text.	unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with §211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§310.305 and 514.80 of this chapter."
Returned drug products **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.204** "…Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1	**Does the manufacturer have a current license?**	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."	Click or tap here to enter text.
☐	☐	☐	2	**Does the manufacturer have a current DEA registration?**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
Organization and Personnel – 21 CFR 211 Subpart B						
☐	☐	☐	3	**Does the organization have a quality control unit that is responsible for approving or rejecting drug products manufactured, processed, and packaged?**	**21 CFR 211.22(a)** "There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company."	Click or tap here to enter text.
☐	☐	☐	4	**Does the quality control unit have adequate laboratory facilities?**	**21 CFR 211.22(b)** "Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					process materials, and drug products shall be available to the quality control unit."	
☐	☐	☐	5	**Does the quality control unit approve or reject all procedures affecting the drug product identity, strength, quality, and purity?**	**21 CFR 211.22(c)** "The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."	Click or tap here to enter text.
☐	☐	☐	6	**Are operations personnel appropriately trained?**	**21 CFR 211.25(a)** "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them."	Click or tap here to enter text.
☐	☐	☐	7	**Are supervisory personnel appropriately trained?**	**21 CFR 211.25(b)** "Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess."	Click or tap here to enter text.
☐	☐	☐	8	**Is the facility adequately staffed for the operations performed?**	**21 CFR 211.25(c)** "There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product."	Click or tap here to enter text.
☐	☐	☐	9	**Are personnel appropriately garbed?**	**21 CFR 211.28(a)** "Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination."	Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	10		**Are personnel practicing good sanitation and health habits?**	**21 CFR 211.28(b)** "Personnel shall practice good sanitation and health habits."	Click or tap here to enter text.
☐	☐	☐	11		**Do supervisors control access to operational areas?**	**21 CFR 211.28(c)** "Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas."	Click or tap here to enter text.
☐	☐	☐	12		**Are personnel showing signs of illness or open wounds prohibited from contact with components or production operations?**	**21 CFR 211.28(d)** "Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products."	Click or tap here to enter text.
			13		**Are records of consultants maintained to include the following:**	**21 CFR 211.34** "Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide."	
☐	☐	☐	13	a	**Name of consultant**		Click or tap here to enter text.
☐	☐	☐	13	b	**Address of consultant**		Click or tap here to enter text.
☐	☐	☐	13	c	**Qualifications**		Click or tap here to enter text.
☐	☐	☐	13	d	**Services provided**		Click or tap here to enter text.
Buildings and Facilities - 21 CFR 211 Subpart C							
☐	☐	☐	14		**Is the facility appropriately constructed to accommodate cleaning, maintenance, and operations?**	**21 C.F.R 211.42(a)** "Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations."	Click or tap here to enter text.
☐	☐	☐	15		**Do storage areas have adequate space for orderly placement of equipment and materials with flow through the building to prevent contamination?**	**21 C.F.R 211.42(b)** "Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					drug products through the building or buildings shall be designed to prevent contamination."	
☐	☐	☐	16	**Are there designated areas for each separate operation occurring within the facility?**	**21 C.F.R 211.42(c)** "Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures: (1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging; (2) Holding rejected components, drug product containers, closures, and labeling before disposition; (3) Storage of released components, drug product containers, closures, and labeling; (4) Storage of in-process materials; (5) Manufacturing and processing operations; (6) Packaging and labeling operations; (7) Quarantine storage before release of drug products; (8) Storage of drug products after release; (9) Control and laboratory operations; (10) Aseptic processing…"	Click or tap here to enter text.
☐	☐	☐	17	**Are controlled substances stored separately in an appropriately secured area?**	**WAC 246-945-565(4)** "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." **21 CFR 1301.72** "(a) Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas: (1) Where small quantities permit, a safe or steel cabinet; (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve. (2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or (3) A vault constructed after September 1, 1971: (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1⁄2 -inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings; (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open; (iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;	

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Yes	No	N/A				
					(v) The door of which vault is equipped with contact switches; and (vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration. (b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas: (1) A safe or steel cabinet as described in paragraph (a)(1) of this section; (2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section; (3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications: (i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section, (ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and: (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or; (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;	

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(4) A cage, located within a building on the premises, meeting the following specifications: (i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are: (a) At least one inch in diameter; (b) Set in concrete or installed with lag bolts that are pinned or brazed; and (c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches; (ii) Having a mesh construction with openings of not more than two and one-half inches across the square, (iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height, (iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and (v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve; (5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage; (6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; (7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in §1301.71(b);…"	
☐	☐	☐	18	**Does the facility have adequately lighting?**	**21 C.F.R 211.44** "Adequate lighting shall be provided in all areas."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	19	**Does the facility have proper ventilation, air filtration, and HVAC including temperature and humidity monitoring when appropriate?** ****Note: Refrigerators temperatures are to be maintained between 2-8°C (36-46°F) and freezers between -25°& -10°C (-13° & 14°F)?** **** Electronic monitoring is acceptable. ****	**21 CFR 211.46** "(a) Adequate ventilation shall be provided. (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product. (c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants. (d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use."	Click or tap here to enter text.
☐	☐	☐	20	**Does the facility have positive pressure potable water with appropriate drainage?**	**21 CFR 211.48** "(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR part 141. Water not meeting such standards shall not be permitted in the potable water system. (b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage."	Click or tap here to enter text.
☐	☐	☐	21	**Is trash and refuse disposed of properly?**	**21 CFR 211.50** "Sewage and refuse. Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner."	Click or tap here to enter text.
☐	☐	☐	22	**Is the facility maintained in a clean and sanitary condition?**	**21 CFR 211.56(a)** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner."	Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	23		**Is the facility maintained in a good state of repair?**	**21 CFR 211.58** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair."	Click or tap here to enter text.
Equipment - 21 CFR 211 Subpart D							
☐	☐	☐	24		**Is suitable equipment used during the manufacturing process?**	**21 CFR 211.63** "Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance."	Click or tap here to enter text.
☐	☐	☐	25		**Is equipment appropriately constructed to prevent contamination of the products manufactured?**	**21 CFR 211.65** "(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. (b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements."	Click or tap here to enter text.
			26		**Is equipment appropriately cleaned and maintained with documentation?**	**21 CFR 211.67** "(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements… (c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§211.180 and 211.182."	Click or tap here to enter text.
☐	☐	☐	26	a	**Assigned personnel**		Click or tap here to enter text.
☐	☐	☐	26	b	**Maintenance and cleaning schedules**		Click or tap here to enter text.
☐	☐	☐	26	c	**Description of maintenance and cleaning operations**		Click or tap here to enter text.
☐	☐	☐	26	d	**Removal of previous batch identification**		Click or tap here to enter text.
☐	☐	☐	26	e	**Equipment protected from contamination**		Click or tap here to enter text.
☐	☐	☐	26	f	**Equipment inspections prior to use**		Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	27	**Is equipment routinely calibrated per written procedures with appropriate records maintained?**	**21 CFR 211.68(a)** "Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained."	Click or tap here to enter text.
☐	☐	☐	28	**Are appropriate controls in place to prevent changes to master production and control records?**	**21 CFR 211.68(b)** "Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system..."	Click or tap here to enter text.
☐	☐	☐	29	**Is a backup file maintained for computerized systems?**	**21 CFR 211.68(b)** "...A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained."	Click or tap here to enter text.
☐	☐	☐	30	**Is the performance of equipment operations cross-checked by a second person?**	**21 CFR 211.68(c)** "Such automated equipment used for performance of operations addressed by §§211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	31	**Are non-fiber releasing filters used?**	**21 CFR 211.72** "Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. The use of an asbestos-containing filter is prohibited."	Click or tap here to enter text.
Control of Components, Drug Product Containers and Closures – 21 C.F.R 211 Subpart E						
☐	☐	☐	32	**Are components, drug product containers, and closures stored appropriately to prevent contamination?**	**21 CFR 211.80(b)** "Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination."	Click or tap here to enter text.
☐	☐	☐	33	**Are bagged or boxed drug product containers and closures stored off the floor with suitable spacing?**	**21 CFR 211.80(c)** "Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection."	Click or tap here to enter text.
☐	☐	☐	34	**Are containers for components or drug product containers or closures identified with a distinctive code and status?**	**21 CFR 211.80(d)** "Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected)."	Click or tap here to enter text.
☐	☐	☐	35	**Are containers of components, drug product containers, and closures examined for damage, broken seals, and contamination upon receipt?**	**21 CFR 211.82(a)** "Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination."	Click or tap here to enter text.
☐	☐	☐	36	**Are containers of components, drug product containers, and closures quarantined prior to approval for release?**	**21 CFR 211.82(b)** "Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area shall conform to the requirements of §211.80."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	37	**Are containers of components, drug product containers, and closures sampled, tested, or examined and released for use by the quality control unit?**	**21 CFR 211.84(a)** "Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit."	Click or tap here to enter text.
☐	☐	☐	38	**Are samples of each shipment of each lot retained for testing or examination in appropriate quantities?**	**21 CFR 211.84(b)** "Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by §211.170."	Click or tap here to enter text.
☐	☐	☐	39	**Have samples been collected per procedure?**	**21 CFR 211.84(c)** "Samples shall be collected in accordance with the following procedures: (1) The containers of components selected shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component. (2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers, or closures. (3) Sterile equipment and aseptic sampling techniques shall be used when necessary. (4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing. 5) Sample containers shall be identified so that the following information can be determined: name of the material sampled, the lot number, the container from which the sample was taken, the date on which the sample was taken, and the name of the person who collected the sample. (6) Containers from which samples have been taken shall be marked to show that samples have been removed from them."	Click or tap here to enter text.
☐	☐	☐	40	**Have samples been examined and tested as required?**	**21 CFR 211.84(d)** "Samples shall be examined and tested as follows:	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used. (2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. (3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals. (4) When appropriate, components shall be microscopically examined. (5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination. (6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use."	
☐	☐	☐	41	**Are lots of components, drug product containers, or closures that do not meet specifications rejected?**	**21 CFR 211.84(e)** "Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under paragraph (d) of this section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	42	**Is stock appropriately rotated so that oldest approved stock is used first?**	**21 CFR 211.86** "Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate."	Click or tap here to enter text.
☐	☐	☐	43	**Are lots of components, drug product containers, or closures retested or reexamined as appropriate for identity, strength, quality, and purity by the quality control unit for approval or rejection?**	**21 CFR 211.87** "Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with §211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure."	Click or tap here to enter text.
☐	☐	☐	44	**Are rejected components, drug product containers, and closures identified and quarantined?**	**21 CFR 211.89** "Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	Click or tap here to enter text.
☐	☐	☐	45	**Are drug product containers and closures reactive, additive, or absorptive?**	**21 CFR 211.94(a)** "Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements."	Click or tap here to enter text.
☐	☐	☐	46	**Do container closure systems provide adequate protection to prevent deterioration or contamination of the drug product?**	**21 CFR 211.94(b)** "Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product."	Click or tap here to enter text.
☐	☐	☐	47	**Are drug product containers and closures clean and/or sterilized to assure they are suitable for their intended use?**	**21 CFR 211.94(c)** "Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated."	Click or tap here to enter text.
Production and Process Controls – 21 CFR 211 Subpart F						
☐	☐	☐	48	**Is documentation of production and process controls recorded and justified including deviations from written procedures?**	**21 CFR 211.100(b)** "Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation	Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						from the written procedures shall be recorded and justified."	
☐	☐	☐	49	**Are batches formulated to provide 100 percent of the labeled or established amount of active ingredient?**		**21 CFR 211.101(a)** "The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient."	Click or tap here to enter text.
			50	**Does repackaged component labeling include:**		**21 CFR 211.101(b)** "Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information: (1) Component name or item code; (2) Receiving or control number; (3) Weight or measure in new container; (4) Batch for which component was dispensed, including its product name, strength, and lot number."	Click or tap here to enter text.
☐	☐	☐	50	(1)	**Component name or item code;**		Click or tap here to enter text.
☐	☐	☐	50	(2)	**Receiving or control number;**		Click or tap here to enter text.
☐	☐	☐	50	(3)	**Weight or measure in new container;**		Click or tap here to enter text.
☐	☐	☐	50	(4)	**Batch for which component was dispensed, including its product name, strength, and lot number?**		Click or tap here to enter text.
			51	**Is each container of component dispensed to manufacturing verified by a second person to assure:**		**21 CFR 211.101(c)** "Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: (1) The component was released by the quality control unit; (2) The weight or measure is correct as stated in the batch production records; (3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under §211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section."	Click or tap here to enter text.
☐	☐	☐	51	(1)	**The component was released by the quality control unit;**		Click or tap here to enter text.
☐	☐	☐	51	(2)	**The weight or measure is correct as stated in the batch production records;**		Click or tap here to enter text.
☐	☐	☐	51	(3)	**The containers are properly identified?**		Click or tap here to enter text.
☐	☐	☐	52	**Is each component either added to the batch by one person and verified by a second person or, if the components are added by automated equipment, only verified by one person?**		**21 CFR 211.211(d)** "Each component shall either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment under §211.68, only verified by one person."	Click or tap here to enter text.
☐	☐	☐	53	**Are actual yields and percentages of theoretical yield determined at the conclusion of each appropriate**		**21 CFR 211.103** "Actual yields and percentages of theoretical yield shall be determined at the conclusion of	Click or tap here to enter text.

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Yes	No	N/A				
				phase of manufacturing, processing, packaging, or holding of the drug product?	each appropriate phase of manufacturing, processing, packaging, or holding of the drug product…"	
☐	☐	☐	54	**Are yield calculations performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person?**	**21 CFR 211.103** "…Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under §211.68, be independently verified by one person."	Click or tap here to enter text.
☐	☐	☐	55	**Are all storage containers, processing lines, and major equipment used during batch production properly identified at all times?**	**21 CFR 211.105(a)** "All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch."	Click or tap here to enter text.
☐	☐	☐	56	**Is identification of major equipment included in batch production records?**	**21 CFR 211.105(b)** "Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code."	Click or tap here to enter text.
☐	☐	☐	57	**Are in-process specifications consistent with or within acceptable variability estimates for drug product final specifications?**	**21 CFR 211.110(b)** "Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications."	Click or tap here to enter text.
☐	☐	☐	58	**Are in-process materials tested for identity, strength, quality, and purity, and approved or rejected by the quality control unit?**	**21 CFR 211.110(c)** "In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	59	**Are rejected in-process materials identified and quarantined to prevent use?**	**21 CFR 211.110(d)** "Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	Click or tap here to enter text.
☐	☐	☐	60	**Are time limits for completion of each phase of production established with any deviations justified and documented?**	**21 CFR 211.111** "When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented."	Click or tap here to enter text.
☐	☐	☐	61	**Is reprocessing performed only after review and approval of the quality control unit?**	**21 CFR 211.115(b)** "Reprocessing shall not be performed without the review and approval of the quality control unit."	Click or tap here to enter text.
Packaging and Labeling Control – 21 CFR 211 Subpart G						
☐	☐	☐	62	**Are labeling and packaging materials representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product?**	**21 CFR 211.122(a)** "…Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product."	Click or tap here to enter text.
☐	☐	☐	63	**Are labeling or packaging materials approved and released for use meeting appropriate written specifications?**	**21 CFR 211.122(b)** "Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable."	Click or tap here to enter text.
☐	☐	☐	64	**Are records maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected?**	**21 CFR 211.122(c)** "Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected."	Click or tap here to enter text.
☐	☐	☐	65	**Are labels and labeling materials for different drug products stored separately with suitable identification and access to the storage area limited to authorized personnel?**	**21 CFR 211.122(d)** "Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	66	**Are obsolete and outdated labels, labeling, and other packaging materials destroyed?**	**21 CFR 211.122(e)** "Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed."	Click or tap here to enter text.
☐	☐	☐	67	**Is use of gang-printed labeling prohibited unless differentiated by size, shape, or color?**	**21 CFR 211.122(f)** "Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color."	Click or tap here to enter text.
☐	☐	☐	68	**Does cut labeling include at least one special control procedure?**	**21 CFR 211.122(g)** "If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures: (1) Dedication of labeling and packaging lines to each different strength of each different drug product; (2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or (3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person. (4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment."	Click or tap here to enter text.
☐	☐	☐	69	**Are printing devices monitored to assure that all imprinting conforms to the print specified in the batch production record?**	**21 CFR 211.122(h)** "Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record."	Click or tap here to enter text.
☐	☐	☐	70	**Is strict control exercised in drug product labeling operations?**	**21 CFR 211.125(a)** "Strict control shall be exercised over labeling issued for use in drug product labeling operations."	Click or tap here to enter text.
☐	☐	☐	71	**Are labeling materials examined to the specifications in the master or batch production records?**	**21 CFR 211.125(b)** "Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	72	**Is there a reconciliation process to evaluate labeling quantity discrepancies?**	**21 CFR 211.125(c)** "Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with §211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with §211.122(g)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers."	Click or tap here to enter text.
☐	☐	☐	73	**Are excess labeling bearing lot or control numbers destroyed?**	**21 CFR 211.125(d)** "All excess labeling bearing lot or control numbers shall be destroyed."	Click or tap here to enter text.
☐	☐	☐	74	**Are returned labeling maintained and stored in a manner to prevent mix-ups and provide proper identification?**	**21 CFR 211.125(e)** "Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification."	Click or tap here to enter text.
☐	☐	☐	75	**Are OTC drug products packaged for retail sales in tamper-evident packaging?**	**21 CFR 211.132(b)(1)** "Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A tamper-evident package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display."	
☐	☐	☐	76	**Are two-piece, hard gelatin capsules for OTC retail sale sealed using tamper-evident technology?**	**21 CFR 211.132(b)(2)** "In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology."	Click or tap here to enter text.
☐	☐	☐	77	**Does OTC drug packaging contain a statement identifying all tamper-evident features?**	**21 CFR 211.132(c)** "(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that: (i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with paragraph (b) of this section; (ii) Is prominently placed on the package; and (iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing. (2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck.""	Click or tap here to enter text.
☐	☐	☐	78	**Is the FDA notified of changes in packaging and labeling for OTC drug products subject to new drug applications?**	**21 CFR 211.132(e)** "OTC drug products subject to approved new drug applications. Holders of approved new drug applications for OTC drug products are required under §314.70 of this chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this section. Changes in packaging and labeling required by this regulation may be made	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					before FDA approval, as provided under §314.70(c) of this chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under §314.70(b) of this chapter."	
☐	☐	☐	79	**Are packaged and labeled products sampled and examined to confirm containers and packages have the correct label with the results documented?**	**21 CFR 211.134** "(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label. (b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling. (c) Results of these examinations shall be recorded in the batch production or control records."	Click or tap here to enter text.
☐	☐	☐	80	**Does drug product labeling bear an appropriate expiration date, unless exempt?**	**21 CFR 211.137** "(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166. (b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in §211.166. (c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products. (d) Expiration dates shall appear on labeling in accordance with the requirements of §201.17 of this chapter. (e) Homeopathic drug products shall be exempt from the requirements of this section. (f) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section. (g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product. (h) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the	Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data."	
Laboratory Controls - 21 CFR 211 Subpart I							
☐	☐	☐	81		**Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any changes, reviewed and approved by the quality control unit?**	**21 CFR 211.160(a)** "The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit."	Click or tap here to enter text.
☐	☐	☐	82		**Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms followed and documented including justification for any deviations?**	**21 CFR 211.160(a)** "…The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified."	Click or tap here to enter text.
			83		**Do laboratory controls include the following:**	**21 CFR 211.160(b)** "Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: (1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of	Click or tap here to enter text.
☐	☐	☐	83	(1)	**Conformity to specifications for the acceptance of each lot of components, containers, closures, and labeling**		Click or tap here to enter text.
☐	☐	☐	83	(2)	**Conformity to specifications for sampling and testing procedures for in-process materials.**		Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	83	(3)	**Conformity to sampling procedures and specifications for drug products**	any component, drug product container, or closure that is subject to deterioration. (2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified. (3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified. (4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."	Click or tap here to enter text.
☐	☐	☐	83	(4)	**Calibration of instruments, apparatus, gauges, and recording devices at suitable intervals?**		Click or tap here to enter text.
☐	☐	☐	84		**Is each batch of drug products tested for conformance to final specifications for identify and strength of active ingredients prior to release?**	**21 CFR 211.165(a)** "For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible."	Click or tap here to enter text.
☐	☐	☐	85		**Is each batch of drug product tested to be free of objectionable microorganisms?**	**21 CFR 211.165(b)** "There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms."	Click or tap here to enter text.
☐	☐	☐	86		**Is acceptance criteria for sampling and testing, including acceptance and rejection levels, adequate to assure batches of drug products meet all specifications and quality control criteria?**	**21 CFR 211.165(d)** "Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	87	**Are test methods established and documented for accuracy, sensitivity, specificity, and reproducibility?**	**21 CFR 211.165(e)** "The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with §211.194(a)(2)."	Click or tap here to enter text.
☐	☐	☐	88	**Are drug products failing to meet established standards or specifications rejected?**	**21 CFR 211.165(f)** "Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria."	Click or tap here to enter text.
☐	☐	☐	89	**Are batches of each drug product tested to determine an appropriate expiration date with records maintained?**	**21 CFR 211.166(b)** "An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined."	Click or tap here to enter text.
☐	☐	☐	90	**Are homeopathic drug products assessed for stability and compatibility to ensure there is no degradation of product for the expected period of use?**	**21 CFR 211.166(c)** "For homeopathic drug products, the requirements of this section are as follows: (1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use. (2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed."	Click or tap here to enter text.
☐	☐	☐	91	**Are drug products purporting to be sterile and/or pyrogen-free tested**	**21 CFR 211.167(a)** "For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				to determine conformance to such requirements?	appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed."	
☐	☐	☐	92	**Are ophthalmic ointments tested for the presence of foreign particles and harsh or abrasive substances?**	**21 CFR 211.167(b)** "For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	93	**Are controlled-release dosage forms tested for conformance to rate of release specifications for each active ingredient?**	**21 CFR 211.167(c)** "For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	94	**Are reserve samples of drug products retained in appropriate quantities for the required time frame?**	**21 CFR 211.170(a)(1)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient."	Click or tap here to enter text.
☐	☐	☐	95	**Are reserve samples of radioactive drug products retained in appropriate quantities for the required time frame?**	**21 CFR 211.170(a)(2)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days."	
☐	☐	☐	96	**Are reserve samples of OTC drug products retained in appropriate quantities for the required time frame?**	**21 CFR 211.170(a)(3)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under §211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient."	Click or tap here to enter text.
☐	☐	☐	97	**Are reserve samples of each lot or batch of drug products stored consistent with product labeling and visually examined at least yearly with results documented?**	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: (1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product…"	
☐	☐	☐	98	**Are reserve samples of each lot or batch of radioactive drug products stored consistent with product labeling and visually examined at the specified intervals with results documented?**	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: … (2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for: (i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days…"	Click or tap here to enter text.
☐	☐	☐	99	**Are reserve samples of each lot or batch of OTC drug products stored**	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				consistent with product labeling and visually examined at least yearly with results documented?	product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: … (3) For an OTC drug product that is exempt for bearing an expiration date under §211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed."	
☐	☐	☐	100	**Are animals used in testing maintained in a suitable manner with appropriate records of their use?**	**21 CFR 211.173** "Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use."	Click or tap here to enter text.
☐	☐	☐	101	**Are non-penicillin containing drug products exposed to cross-contamination with penicillin tested for the presence of penicillin?**	**21 CFR 211.176** "If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Records and Reports – 21 CFR 211 Subpart J						
☐	☐	☐	102	**Are production, control, and distribution records of drug products, components, containers, closures, and labeling retained for 1 year after the expiration date, or 3 years after distribution for OTC drug products lacking expiration dating?** ****Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.**	**21 CFR 211.180** "(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the batch. (b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling."	Click or tap here to enter text.
☐	☐	☐	103	**Are production, control, and distribution records readily available during the retention period at the place where the activities occurred?** ****Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.**	**21 CFR 211.180(c)** "All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph."	Click or tap here to enter text.
☐	☐	☐	104	**Are written records maintained so data can be used to annually evaluate the quality standards of each drug product?**	**21 CFR 211.180(e)** "Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures…"	Click or tap here to enter text.
☐	☐	☐	105	**Do signed and dated equipment cleaning and maintenance logs include the date, time, product, and lot number of each batch processed in chronological order?**	**21 CFR 211.182** "A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is	Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under §211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order."	
			106	**Do component, container, closure, and labeling records include:**		**21 CFR 211.184** Component, drug product container, closure, and labeling records shall include "(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in §211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known. (b) The results of any test or examination performed (including those performed as required by §211.82(a), §211.84(d), or §211.122(a)) and the conclusions derived therefrom. (c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure. (d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§211.122(c) and 211.130(c). (e) The disposition of rejected components, drug product containers, closure, and labeling."	Click or tap here to enter text.
☐	☐	☐	106	(a)	**The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s); the receiving code; and the date of receipt**		Click or tap here to enter text.
☐	☐	☐	106	(b)	**The results of any test or examination performed**		Click or tap here to enter text.
☐	☐	☐	106	(c)	**An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component**		Click or tap here to enter text.
☐	☐	☐	106	(d)	**Documentation of the examination and review of labels and labeling**		Click or tap here to enter text.
☐	☐	☐	106	(e)	**The disposition of rejected components, drug product containers, closure, and labeling?**		Click or tap here to enter text.

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Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	107		**Do master production and control records for each batch include the batch size, date, and signatures?**	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."	Click or tap here to enter text.
☐	☐	☐	108		**Do master production and control records include:**	**21 CFR 211.186(b)** "Master production and control records shall include: (1) The name and strength of the product and a description of the dosage form; (2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit; (3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic; (4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records; (5) A statement concerning any calculated excess of component; (6) A statement of theoretical weight or measure at appropriate phases of processing; (7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to §211.192 is required; (8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;	Click or tap here to enter text.
☐	☐	☐	108	(1)	**Name, strength, and dosage form of the product**		Click or tap here to enter text.
☐	☐	☐	108	(2)	**Name and weight or measure of each active ingredient**		Click or tap here to enter text.
☐	☐	☐	108	(3)	**List of components designated by name or code indicating any special quality characteristic**		Click or tap here to enter text.
☐	☐	☐	108	(4)	**Weight or measure of each component**		Click or tap here to enter text.
☐	☐	☐	108	(5)	**Statement of any calculated excess of component**		Click or tap here to enter text.
☐	☐	☐	108	(6)	**Statement of theoretical weight at appropriate phases of processing**		Click or tap here to enter text.
☐	☐	☐	108	(7)	**Statement of maximum and minimum theoretical yield expected**		Click or tap here to enter text.
☐	☐	☐	108	(8)	**Description of containers, closures, packaging materials, copy of the label, and all other labeling**		Click or tap here to enter text.
☐	☐	☐	108	(9)	**Complete manufacturing and control instructions, sampling and testing procedures, and specifications?**		Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed."	
☐	☐	☐	109	**Do batch production and control records include a copy of the signed and dated master production record?**	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: (a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;…"	Click or tap here to enter text.
☐	☐	☐	110	**Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished?**	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: … (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: (1) Dates; (2) Identity of individual major equipment and lines used; (3) Specific identification of each batch of component or in-process material used; (4) Weights and measures of components used in the course of processing; (5) In-process and laboratory control results; (6) Inspection of the packaging and labeling area before and after use; (7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing; (8) Complete labeling control records, including specimens or copies of all labeling used; (9) Description of drug product containers and closures; (10) Any sampling performed; (11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					performed by automated equipment under §211.68, the identification of the person checking the significant step performed by the automated equipment. (12) Any investigation made according to §211.192. (13) Results of examinations made in accordance with §211.134."	
☐	☐	☐	111	**Are drug product production and control records, including packaging and labeling records, reviewed and approved by the quality control unit?**	**21 CFR 211.192** "All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup."	Click or tap here to enter text.
☐	☐	☐	112	**Do laboratory records include complete data derived from all tests necessary to assure compliance with specifications and standards?**	**21 CFR 211.194(a)** "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows: (1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing. (2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, AOAC INTERNATIONAL, Book of	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					Methods,1 or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use… (3) A statement of the weight or measure of sample used for each test, where appropriate. (4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested. (5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors. (6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested. (7) The initials or signature of the person who performs each test and the date(s) the tests were performed. (8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards."	
☐	☐	☐	113	**Are records maintained of any modification of an established method employed in testing?**	**21 CFR 211.194(b)** "Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method."	Click or tap here to enter text.
☐	☐	☐	114	**Are records maintained of any testing and standardization of laboratory reference standards, reagent, and standard solutions?**	**21 CFR 211.194(c)** "Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	115	**Are records maintained of calibration of laboratory equipment?**	**21 CFR 211.194(d)** "Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by §211.160(b)(4)."	Click or tap here to enter text.
☐	☐	☐	116	**Are records maintained of stability testing?**	**21 CFR 211.194(e)** "Complete records shall be maintained of all stability testing performed in accordance with §211.166."	Click or tap here to enter text.
☐	☐	☐	117	**Do distribution records contain the name and strength of the product, dosage form, name and address of the consignee, date and quantity shipped, and lot number?**	**21 CFR 211.196** "Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product. For compressed medical gas products, distribution records are not required to contain lot or control numbers."	Click or tap here to enter text.
☐	☐	☐	118	**Do written records of complaints include all required elements and are they maintained for the specified time period?** ****Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.**	**21 CFR 211.198(b)** "A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, such written records shall be maintained for 3 years after distribution of the drug product. (1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant. (2) Where an investigation under §211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with §211.180(c).	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) Where an investigation under §211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination."	
Returned and Salvaged Drug Products – 21 CFR 211 Subpart K						
☐	☐	☐	119	**Are returned drug products examined, tested, or investigated prior to reprocessing, if applicable, with results documented?**	**21 CFR 211.204** "Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of §211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	120	**Are drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures**	**21 CFR 211.208** "Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a)	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				prohibited from salvage and return to the marketplace?	evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this section."	
Controlled Substances						
☐	☐	☐	121	**Does the manufacturer maintain records of receipt and distribution of all controlled substances?**	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from Manufacturers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;…"	Click or tap here to enter text.
☐	☐	☐	122	**Are records of Schedule II drugs maintained separately from all other controlled substance records?**	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	Click or tap here to enter text.
☐	☐	☐	123	**Does the manufacturer have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?**	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	124	**Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?**	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					21 C.F.R 1304.04(h)(3) "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	
☐	☐	☐	125	**Is an inventory of controlled substances being performed every 2 years?** **** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances. ****	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	Click or tap here to enter text.
☐	☐	☐	126	**Does the manufacturer have power of attorney forms for ordering schedule II controlled substances?**	**21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.
☐	☐	☐	127	**Has the manufacturer reported a loss of controlled substances in the previous 24 months to the DEA and the Pharmacy Quality Assurance Commission?**	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-9945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	
Additional Federal and Washington State Specific Regulations						
☐	☐	☐	128	**Are solid dosage form legend drugs, labeling and packaging, clearly marked or imprinted as required?**	**21 CFR 206.10(a)** "Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature." **RCW 69.41.200** "(1) No legend drug in solid dosage form may be manufactured or commercially distributed within this state unless it has clearly marked or imprinted on it an individual symbol, number, company name, words, letters, marking, or National Drug Code number identifying the drug and the manufacturer or distributor of such drug. (2) No manufacturer or distributor may sell any legend drug contained within a bottle, vial, carton, or other container, or in any way affixed or appended to or enclosed within a package of any kind designed or intended for delivery in such container or package to an ultimate consumer within this state unless such container or package has clearly and permanently marked or imprinted on it an individual symbol, number, company name, words, letters, marking, or National Drug Code number identifying the drug and the manufacturer or distributor of such drug.	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) Whenever the distributor of a legend drug does not also manufacture it, the names and places of businesses of both shall appear on the stock container or package label in words that truly distinguish each."	
☐	☐	☐	129	**Does the manufacturer provide to the commission printed material identifying each imprint used by the manufacturer?**	**RCW 69.41.220** "Each manufacturer and distributor shall publish and provide to the commission by filing with the department printed material which will identify each current imprint used by the manufacturer or distributor. The commission shall be notified of any change by the filing of any change with the department…"	Click or tap here to enter text.
☐	☐	☐	130	**Does the manufacturer have exemptions for drug products that are infeasible to imprint?**	**RCW 69.41.250(1)** "The commission, upon application of a manufacturer, may exempt a particular legend drug from the requirements of RCW 69.41.050 and 69.41.200 through 69.41.260" on the grounds that imprinting is infeasible because of size, texture, or other unique characteristics." **21 CFR 206.7** "(a) The following classes of drug products are exempt from requirements of this part: (1) Drug products intended for use in a clinical investigation under section 505(i) of the act, but not including drugs distributed under a treatment IND under part 312 of this chapter or distributed as part of a nonconcurrently controlled study. Placebos intended for use in a clinical investigation are exempt from the requirements of this part if they are designed to copy the active drug products used in that investigation. (2) Drugs, other than reference listed drugs, intended for use in bioequivalence studies. (3) Drugs that are extemporaneously compounded by a licensed pharmacist, upon receipt of a valid prescription for an individual patient from a practitioner licensed by law to prescribe or administer drugs, to be used solely by the patient for whom they are prescribed. (4) Radiopharmaceutical drug products. (b) Exemption of drugs because of size or unique physical characteristics: (1) For a drug subject to premarket approval, FDA may provide an exemption from the requirements of §206.10 upon a showing that the product's size, shape, texture, or	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					other physical characteristics make imprinting technologically infeasible or impossible… (2) Any product not subject to premarket approval is exempt from the requirement of §206.10 if, based on the product's size, shape, texture, or other physical characteristics, the manufacturer or distributor of the product is prepared to demonstrate that imprinting the dosage form is technologically infeasible or impossible."	
☐	☐	☐	131	**Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?**	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(7)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	Click or tap here to enter text.
☐	☐	☐	132	**Does the manufacturer verify that the person they purchase drug stock from is authorized to distribute drugs?**	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: … (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs to that purchaser or recipient;…"	Click or tap here to enter text.
☐	☐	☐	133	**Does the manufacturer verify that the person to whom they distribute is authorized to receive drug stock?**	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: … (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug;…"	Click or tap here to enter text.

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Read this Page Carefully

Pharmacy Quality Assurance Commission

~~2022~~ 2023 Wholesaler Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Wholesalers are responsible for ensuring compliance with all applicable state and federal laws. Failure to complete this annual worksheet within the month of March and~~or~~ within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a wholesaler's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The wholesaler must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not assume compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the designated person to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in blue are questions that will be focused on during routine wholesaler inspections.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov. View translated versions of this statement here.

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Wholesaler Self-Inspection Worksheet

All Wholesaler responsible managers (or equivalent managers) ***must*** complete and sign this self-inspection worksheet annually within the month of March and~~or~~ within 30 days of becoming the responsible manager. The form must be available for inspection as required by WAC 246-945-005.
Do not send to the commission office.

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Date Wholesaler Self-Inspection was performed: Click or tap to enter a date. (mm/dd/yy)

Change in Responsible Manager and effective date of change: Click or tap here to enter text.

Print Name of Responsible Manager: Click or tap here to enter text.

Signature of Responsible Manager: Click or tap here to enter text.

Responsible Manager E-mail: Click or tap here to enter text.

Wholesaler: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Wholesaler License #: Click or tap here to enter text.

Endorsements: ☐ Controlled Substances ☐ Export Wholesaler

Document and Record Review

Please provide the location of these documents in the facility ~~Where are the following items located inside the wholesaler~~ (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.

	Rule Reference
Wholesaler Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Wholesaler License Location: Click or tap here to enter text.	**RCW 18.64.046(1)** "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified…"
DEA Registration Location: Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**21 CFR 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms

	222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft…"
Suspicious Order Reports Location: Click or tap here to enter text. **Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.** **Exemption Attestation**	**WAC 246-945-585(1)** "(a)Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to:(i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(b)** "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date

	of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." **21 CFR 1305.13(d)** "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." **21 CFR 1305.13(e)** "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Action
General Licensing						
☐	☐	☐	1	**Does the wholesaler have a current license?**	**RCW 18.64.046(1)** "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified for the period ending on a date to be determined by the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					WAC 246-945-246(1) "Every wholesaler who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes: (a) In-state and out-of-state pharmaceutical wholesalers; (b) Out-of-state manufacturer that distribute or sell drugs into Washington; (c) Virtual wholesalers; (d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington; (e) Outsourcing facilities required to be registered with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) that are located in Washington, or distribute or sell drugs into Washington; and (f) Reverse distributors."	
☐	☐	☐	2	**Does the wholesaler have a current DEA registration?**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
General Standards						
☐	☐	☐	3	**Does the wholesaler maintain a current list of all persons responsible for drug access, distribution, handling, and their training?**	**WAC 246-945-580** "(1) A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (2) A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities."	Click or tap here to enter text.
☐	☐	☐	4	**Is the facility appropriately constructed and equipped to accommodate cleaning, maintenance, and operations?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations…"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	5	**Does the facility have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (b) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security…" **WAC 246-945-565(2)** "If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected."	Click or tap here to enter text.
☐	☐	☐	6	**Does the facility have a quarantine area for drugs that are unsuitable for distribution?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;…" **WAC 246-945-565 (5)** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards."	Click or tap here to enter text.
☐	☐	☐	7	**Is the facility maintained in a clean and orderly condition?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (d) Be maintained in a clean and orderly condition;…"	Click or tap here to enter text.
☐	☐	☐	8	**Is the facility free from infestation?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (e) Be free from infestation of any kind;…"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	9	**Is the facility a commercial location?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (f) Be a commercial location and not a personal dwelling or residence;	Click or tap here to enter text.
☐	☐	☐	10	**Does the facility have secure and confidential storage of information?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information;…"	Click or tap here to enter text.
☐	☐	☐	11	**Does the facility have a method of inventory control to detect theft, counterfeiting, or drug diversion?**	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (h) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs."	Click or tap here to enter text.
☐	☐	☐	12	**Is the outside of the facility well-lit and is it appropriately secured with limited access?**	**WAC 246-945-560(2)** "Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (a) Access from outside the premises must be kept to a minimum and well controlled; (b) The outside perimeter of the premises must be well lit; (c) Entry into areas where drugs are held must be limited to authorized personnel; (d) Facilities must be equipped with an alarm system to detect entry after hours; and (e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering."	Click or tap here to enter text.
☐	☐	☐	13	**Does the facility have temperature and humidity monitoring devices?** **Must follow 2-year recordkeeping requirements**	**WAC 246-945-565(3)** "Temperature and humidity recording equipment, devices, and/or logs shall be used to document proper storage of drugs."	Click or tap here to enter text.
☐	☐	☐	14	**Are refrigerators temperatures maintained between 2-8°C (36-46°F)?** ** Electronic monitoring is acceptable. **	**WAC 246-945-565 Wholesaler—**Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF), to preserve product	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Re-questors may also contact USP directly to obtain copies.	
☐	☐	☐	15	**Are freezers between -25°& -10°C (-13° & 14°F)?**	**WAC 246-945-565 Wholesaler—**Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF), to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Re-questors may also contact USP directly to obtain copies.	Click or tap here to enter text.
☐	☐	☐	16	**Are controlled substances stored separately from noncontrolled substances and secured?**	**WAC 246-945-565(4)** "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." ***See 21 CFR 1301.72 for the requirements for transferring controlled substance prescriptions.**	Click or tap here to enter text.
☐	☐	☐	17	**Are shipments inspected upon arrival and prior to departure from the facility?**	**WAC 246-945-570** "(1) Each outside shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. (2) Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents."	Click or tap here to enter text.
☐	☐	☐	18	**Does the facility verify that the person they purchase drug stock from is authorized to distribute drugs?**	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs to that purchaser or recipient…"	Click or tap here to enter text.
☐	☐	☐	19	**Does the facility verify that the person to whom they distribute is authorized to receive drug stock?**	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state:	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug…"	
Policies and Procedures **Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets and binders).**						
☐	☐	☐	20	**Does the wholesaler have policies and procedures in place for the following:** **(a) Receipt** **(b) Security** **(c) Storage** **(d) Inventory** **(e) Transport** **(f) Shipping** **(g) Report of losses** **(h) Inventory records** **(i) Recalls** **(j) Staff training** **(k) Suspicious order monitoring** **(l) Emergent need** **(m) Integrity and confidentiality of information**	**WAC 246-945-590** "Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures: (1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: (a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or (b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market. (2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency. (3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs. (4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements. (6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies as required to the FDA, commission and/or appropriate federal or state agency upon discovery of such discrepancies. (7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA. (8) Procedures addressing: (a) The design and operation of the suspicious order monitoring and reporting system; (b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following: (i) The wholesaler's suspicious order monitoring system; (ii) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and (iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities. (9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs." **WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					procedures to protect the integrity and confidentiality of information…"	
Recordkeeping						
☐	☐	☐	21	**Are complete records of receipt and distribution of drugs maintained?**	**WAC 246-945-575** "Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. The records must include at least: (a) The source of the drugs, including the name and principal address of the seller or transferor; (b) The identity and quantity of the drugs received and distributed or disposed of; and (c) The dates of receipt and distribution or other disposition of the drugs."	Click or tap here to enter text.
☐	☐	☐	22	**Are records of suspicious orders and zero reports maintained and reported to the pharmacy commission in the appropriate time?**	**WAC 246-945-585(1)** "Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission. (a) Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to: (i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	23	**Are due diligence measures being followed to identify customers ordering or seeking to order controlled substances or drugs of concern?**	**WAC 246-945-585(2)** Except as provided in subsection (3) of this section, a wholesaler shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary: (a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information; (b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished; (c) Review of drug utilization reports; and (d) Obtaining and conducting a review of the following: (i) Methods of payment accepted and in what ratios; (ii) The ratio of controlled versus noncontrolled prescriptions and overall sales; (iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and (iv) The ratio of out-of-state patients served compared to in-state patients.	Click or tap here to enter text.
☐	☐	☐	24	**If in an initial sale is conducted for an emergent need without performing the due diligence measures in WAC 246-945-585(2), are the provided criteria met?**	**WAC 246-945-585(3)** A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (2) of this section if all of the following apply: (a) The sale is to a new customer; (b) The wholesaler documents that the order is to meet an emergent need; (c) The wholesaler completes the requirements of subsection (2) of this section no later than sixty business days from the date of sale.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	25	**Are existing customers providing explanation(s) when a request to purchase a controlled substance or drug of concern exceeds established limitations?**	**WAC 246-945-585 (4)** A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.	Click or tap here to enter text.
☐	☐	☐	26	**Are records of potential diversion activity maintained and reported to the pharmacy commission in the appropriate time?**	**WAC 246-945-585 (5)** Any customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell, shall be electronically reported to the commission. Such reports shall include: (a) Customer name; (b) Customer address; (c) DEA number; (d) State license number(s); (e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk; and (f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.	Click or tap here to enter text.
Controlled Substances						
☐	☐	☐	27	**Are complete records of controlled substance maintained?**	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;	Click or tap here to enter text.
☐	☐	☐	28	**Are records of Schedule II drugs maintained separately from all other controlled substance records?**	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records." **21 C.F.R 1304.04(h)** "Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy."	
☐	☐	☐	29	**Does the wholesaler have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?**	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	30	**Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?**	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 C.F.R 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	31	**Is an inventory of controlled substances being performed every 2 years?** An inventory of controlled substances must be completed within 30 days of a new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances.	**WAC 246 945 040(1)** "The commission adopts 21 CFR as its own. The following sections do not apply: Sec. 1301.13, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1303, Sec. 1308.41-.45, and Sec. 1316.31-.67. Any inconsistencies between 21 CFR Sec. 1300 through 1321 and this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board. **WAC 246-945-040(3)** Recordkeeping and Inventory. Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers,	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11. **21 CFR 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. (d) Inventory date for newly controlled substances. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section. (e) Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors. Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below. (2) Inventories of distributors**.** Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	32	**Does the wholesaler have power of attorney forms for ordering schedule II controlled substances?**	**21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.
☐	☐	☐	33	**Has the wholesaler reported a loss of controlled substances in the previous 24 months to the DEA and the pharmacy commission?**	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-9945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.

Read this Page Carefully

Pharmacy Quality Assurance Commission

~~2022~~ 2023 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and~~or~~ within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a HCE's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an **Inspection Report with Noted Deficiencies**. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not **assume** compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in blue are questions that will be focused on during routine HCE inspections.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov. View translated versions of this statement here.

Style Definition: self-insp sections

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Health Care Entity (HCE) Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of HCEs **must** complete and sign this self-inspection worksheet within the month of March and~~or~~ within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

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Date responsible pharmacy manager inspection was performed: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date.

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

Pharmacy: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Pharmacy License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	Do pharmacy personnel engage in non-sterile compounding of medications? **If yes, please complete the 2021 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.**
☐	☐	Do pharmacy personnel engage in sterile compounding? **If yes, you must also complete the 2021 Sterile Compounding Self-Inspection Addendum. (*New*) If compounding falls under the 'immediate use exemption' as interpreted by the commission *and* is in the retail/community pharmacy setting then the sterile compounding self-inspection worksheet does not need to be completed.**

Document and Record Review

~~Where are the following items located inside the HCE~~Please provide the location of these documents in the facility (be as specific as possible, there can be many filing cabinets and binders)~~.?~~ The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents **you are also confirming your compliance with the referenced rule**.

	Rule Reference
Responsible Pharmacy Manager Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Health Care Entity License Location: Click or tap here to enter text.	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."
DEA Registration Location: Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. **(2)** Inventories and records of controlled substances listed in Schedules III, IV, and V

	Rule Reference
	shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **21 CFR. 1305.13(e)** "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR. 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR. 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR. as its own." **21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the

	Rule Reference
	commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: **(a)** Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. **(b)** Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Action
General Licensing						
☐	☐	☐	1	**Does the Health Care Entity (HCE) have a current license?**	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."	Click or tap here to enter text.
☐	☐	☐	2	**Does the HCE have a current DEA registration?**	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
☐	☐	☐	3	**Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?**	**WAC 246-945-310** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	4	**Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other**	**RCW 69.45.040(2)** "Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				restricted items from unauthorized access? **Including samples under the control of the HCE**	**WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	
☐	☐	☐	5	**Is the facility properly equipped to ensure proper operation, prescription preparation, and product integrity?**	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	6	**Does the facility have a designated responsible pharmacy manager?**	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: **(a)** By the date of opening; and **(b)** Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	7	**Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?**	**WAC 246-945-410(10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: **(a)** A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or **(b)** A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or **(c)** The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	8	**Are medication refrigerator temperatures maintained between 2- 8°C (36-46°F)?** ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	9	**Are medication freezer temperatures maintained between -25°& -10°C (-13° & 14°F) or within acceptable range based on product packaging?**	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				** Electronic monitoring is acceptable. **		
☐	☐	☐	10	**Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label?** **Including samples under the control of the HCE**	**RCW 69.45.040(3)** "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. **(4)** Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	11	**Is all drug stock in date?** **Including OTC medications and samples under the control of the HCE** *It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.*	**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **RCW 69.45.040(5)** "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
Policies and Procedures						
Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets).						
☐	☐	☐	12	**Does the HCE have policies and procedures in place for the following:** a) Purchasing b) Ordering c) Storing d) Compounding	**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	Click or tap here to enter text.

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				e) Delivering f) Dispensing g) Administration		
☐	☐	☐	13	**Does the HCE have policies and procedures addressing administration of patient owned medications?**	**WAC 246-945-440** "Facilities shall develop written policies and procedures for the administration of patient owned medications."	Click or tap here to enter text.
☐	☐	☐	14	**Does the HCE accept dispensed drugs or prescription devices for return and reuse appropriately?**	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: **(a)** Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. **(b)** Those that qualify for return under the provisions of chapter 69.70 RCW."	Click or tap here to enter text.
☐	☐	☐	15	**Does the HCE accept dispensed drugs or prescription devices for return and destruction appropriately?**	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: **(a)** The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; **(b)** The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or **(c)** The return and destruction is in compliance with the facility's policies and procedures."	Click or tap here to enter text.
☐	☐	☐	16	**Does the HCE have policies and procedures addressing computer system downtime?**	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." **WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Recordkeeping						
☐	☐	☐	17	**Are complete patient medical records maintained in either paper or electronic format?**	**WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417."	Click or tap here to enter text.
☐	☐	☐	18	**If applicable, does the HCE maintain electronic record system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care?**	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care." **WAC 246-945-417(7)** HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
☐	☐	☐	19	**Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?**	**WAC 246-945-417(3)** "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration."	Click or tap here to enter text.
☐	☐	☐	20	**If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417?**	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." **WAC 246-945-417** "**(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. **(a)** Systems must prevent auto-population of user identification information. **(b)** Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					the identity of each individual involved in each step of the off-site pharmacy services. **(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. **(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. **(4)** The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained. **(5)** The pharmacy shall maintain records in accordance with WAC 246-945-020. **(6)** Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." **WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	21	**Are suitable record of drugs readily retrievable or maintained separately from all other records?** **Including drug samples under the control of the HCE**	**RCW 18.64.470** "Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with."	Click or tap here to enter text.
☐	☐	☐	22	**Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?**	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(7)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	Click or tap here to enter text.
Controlled Substances						
☐	☐	☐	23	**Are all controlled substances in the HCE locked and secured to prevent unauthorized access?**	**WAC 246-945-040(1)** "The commission adopts 21 CFR. as its own." **21 CFR. 1301.75(a)** "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. **(b)** Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet." **WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	24	**Does the HCE maintain records of receipt and distribution of all controlled substances?**	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: **(a)** Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; **(b)** Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; **(d)** For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR. Sec. 1307.11."	Click or tap here to enter text.
☐	☐	☐	25	**Are records of Schedule II drugs maintained separately from all other controlled substance records?**	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	Click or tap here to enter text.
☐	☐	☐	26	**Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?**	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	27	**Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?**	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 CFR 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	28	**Is an inventory of controlled substances being performed every 2 years?** **Including controlled substance samples under the control of the HCE** **An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances.**	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	Click or tap here to enter text.
☐	☐	☐	29	**Does the HCE have power of attorney forms for ordering schedule II-controlled substances?**	**21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.
☐	☐	☐	30	**Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months?**	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Dispensing – HCEs that do not dispense for use outside the HCE may skip question numbers 32-47 (please only answer question 31)						
☐	☐	☐	31	**Does the HCE dispense prescription medications to patients for at home use?**	**RCW 18.64.450(4)** "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	Click or tap here to enter text.
☐	☐	☐	32	**If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?**	**RCW 18.64.450(4)** "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage."	Click or tap here to enter text.
☐	☐	☐	33	**Does the HCE have valid prescription records for all drugs dispensed to patients?**	**WAC 246-945-410(7)** "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." **WAC 246-945-011(1)** "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." **(2)** A prescription shall be considered invalid if: **(a)** At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; **(b)** The prescription does not contain the required information as provided in WAC 246-945-010; **(c)** The prescription is expired; or **(d)** The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: **(a)** The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. **(b)** The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	Click or tap here to enter text.
☐	☐	☐	34	**Are all non-controlled legend drugs prescribed orally promptly transcribed to a**	**WAC 246-945-010(8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				written or electronic prescription?	prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	
☐	☐	☐	35	**Do all prescriptions for non-controlled legend drugs include all required elements?** a) Prescriber's Name b) Name of Patient/Authorized Entity/Animal Name and Species c) Date of Issuance d) Drug Name, Strength, and Quantity e) Directions for Use f) Number of Refills g) Substitution Directions h) Prescribers Signature i) If written, on Tamper-Resistant Paper	**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: **(a)** Prescriber's name; **(b)** Name of patient, authorized entity, or animal name and species; **(c)** Date of issuance; **(d)** Drug name, strength, and quantity; **(e)** Directions for use; **(f)** Number of refills (if any); **(g)** Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; **(h)** Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and **(i)** If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"	Click or tap here to enter text.
☐	☐	☐	36	**Do all prescriptions for controlled substances include additional required elements?** a) Elements from Question 38 b) Patient's Address c) Dosage Form d) Prescriber's Address e) Prescriber's DEA Number	**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: **(a)** Patient's address; **(b)** Dosage form; **(c)** Prescriber's address; **(d)** Prescriber's DEA registration number; and **(e)** Any other requirements listed in 21 CFR., Chapter II."	Click or tap here to enter text.
☐	☐	☐	37	**Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?** **Includes drug samples under the control of the HCE**	**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "**(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: **(a)** Drug quantity; **(b)** The number of refills remaining, if any; **(c)** The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; **(d)** The name and species of the patient, if a veterinary prescription; and **(e)** The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity… **(3)** For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: **(a)** The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; **(c)** The characteristics of the patient's container, if the drug is repackaged for dispensing; **(d)** The expected conditions to which the drug may be exposed; **(e)** The expected length of time of the course of therapy; and **(f)** Any other relevant factors."	
☐	☐	☐	38	**Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication**	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR., Part 1700, unless: **(a)** Authorization is received from the prescriber to dispense in a container that is not child-resistant.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				packages; blister packs, med-minders, etc.) ** Please see the FAQ on commission website. ** ** Best practice: It is recommended that these authorizations are updated annually. **	**(b)** Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	
☐	☐	☐	39	**Is supplemental information provided to the patient with each dispensed prescription?**	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325." **WAC 246-945-325** **(1)** The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient. **(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.**	Click or tap here to enter text.
☐	☐	☐	40	**Are electronic prescriptions maintained appropriately?**	**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
Pharmacist Professional Requirements						
☐	☐	☐	41	**Unless an exception applies, does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery?**	**WAC 246-945-001(29)** "'Drug utilization review" includes, but is not limited to, the following activities: **(a)** Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; **(b)**	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				OR **If a pharmacist is involved in the dispensing process, is drug utilization review completed?**	Evaluation of prescriptions and patient records for duplication of therapy; **(c)** Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and **(d)** Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur **except in emergent medical situations, or if**: **(a)** The drug is a subsequent dose from a previously reviewed prescription; **(b)** The prescriber is in the immediate vicinity and controls the drug dispensing process; **(c)** The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or **(d)** Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
☐	☐	☐	42	**If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling?**	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.

WA Pharmacy Quality Assurance Commission

~~2023~~ 2023 Responsible Manager
Pharmacy Self-Inspection Worksheet

USP 800 – Hazardous Drugs Addendum

ATTENTION: Responsible Manager or Equivalent

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March ~~or~~ and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace **U.S. Pharmacopeia (USP) <800> Hazardous Drugs – Handling in Healthcare Settings**. (NOTE: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

You should be familiar with WACs 296-62-500 through 296-62-50055 when handling hazardous drug preparations. Please view the commission's policy statement on the Regulation of the Handling of Hazardous Drugs (PDF), which includes the expectations for compliance with L&I's rules on Hazardous Drugs as well as the commission's approach to USP <797> and USP <800>.

This self-inspection worksheet applies only to activities performed by pharmacy personnel. Other healthcare professionals are regulated by their own boards and commissions.

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible manager: _____

General Rule Reference - Applies to all questions throughout the worksheet.
RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
List of Hazardous Drugs							
			1.		Is there a list of HDs that the entity handles? ****Items on the current NIOSH list must be included.****	**USP Chapter 800- 2 LIST OF HAZARDOUS DRUGS** The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list. The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. Drugs on the NIOSH list that must follow the requirements in this chapter include: any HD API, any antineoplastic requiring HD manipulation… If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter. The assessment of risk must, at a minimum, consider the following: type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only); dosage form; risk of exposure; packaging; manipulation. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.	
			2.		Is this list reviewed at least every 12 months?		
			3.		Are newly identified HDs added to the entity list of HDs?		
			4.		Is an assessment of risk performed on eligible HDs?		
			5.		If an assessment is not completed, are all HDs handled with all containment strategies defined in this chapter?		
			6.		Does the assessment of risk include the following:		
			6.	a	Type of HD		
			6.	b	Dosage form		
			6.	c	Risk of exposure		
			6.	d	Packaging		
			6.	e	Manipulation		
			7.		If an assessment of risk approach is taken, does the entity document what alternative containment strategies and/or work practices are being employed for specific		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				dosage forms to minimize occupational exposure?		
			8.	Is the assessment of risk reviewed at least every 12 months?		
Responsibilities of Personnel Handling Hazardous Drugs						
			9.	Does the entity have a qualified and trained designated person?	**USP Chapter 800- 4 RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS** Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team. The designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results. All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.	
			10.	Does the designated person thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team?		
			11.	Is the designated person responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results?		
Facilities and Engineering Controls						
			12.	Are HDs handled under conditions that promote patient safety, worker safety, and environmental protection?	**USP Chapter 800- 5 FACILITIES AND ENGINEERING CONTROLS** HDs must be handled under conditions that promote patient safety, worker safety, and environmental	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			13.		Do areas where HDs are handled have a hazard sign displayed before the entrance?	protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling. HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure. Designated areas must be available for: receipt and unpacking; storage of HDs; nonsterile HD compounding (if performed by the entity); sterile HD compounding (if performed by the entity). Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.	
			14.		Does the HD handling area have restricted access?		
			15.		Are HD handling areas located away from breakrooms and refreshment areas for personnel, patients, or visitors?		
			16.		Does the facility have areas designated for:		
			16.	a	Receipt and unpacking		
			16.	b	Storage of HDs		
			16.	c	Nonsterile HD compounding (if performed by the entity)		
			16.	d	Sterile HD compounding (if performed by the entity)		
			17.		Are antineoplastic HDs and HD APIs unpacked in neutral/normal or negative pressure areas?	**USP Chapter 800- 5.1 RECEIPT** Antineoplastic HDs and all HD APIs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.	
			18.		Does the facility ensure that HDs are not unpacked in sterile compounding areas or in positive pressure areas?		
			19.		Are HDs stored in a manner to prevent spills or breaks?	**USP Chapter 800- 5.2 STORAGE** HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.	
			20.		Are all antineoplastic HDs requiring manipulation, other than counting or repackaging of final dosage forms, and any HD APIs stored separately from non-HDs?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			21.	Are antineoplastic HDs that require manipulation and all HD APIs stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 ACPH?		Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Nonantineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.	
			22.	Are refrigerated antineoplastic HDs stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH?			
			23.	Does sterile or nonsterile compounding of HDs occur in a C-PEC located in a C-SEC?		**USP Chapter 800- 5.3 COMPOUNDING** Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile and nonsterile compounding must: be externally vented; be physically separated (i.e., a different room from other preparation areas); have an appropriate air exchange (e.g., ACPH); have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas. The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding. If there is any loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately per the manufacturer's recommendations. Once the C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and	
			24.	Does the C-SEC used for sterile and nonsterile compounding include:			
			24.	a	External ventilation		
			24.	b	Physical separation		
			24.	c	Appropriate air exchange		
			24.	d	Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas		
			25.	Does the C-PEC operate continuously if it supplies some or			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				all of the negative pressure in the C-SEC or if it is used for sterile compounding?	wait the manufacturer-specified recovery time before resuming compounding. A sink must be available for hand washing. An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. Water sources and drains must be located at least 1 meter away from the C-PEC. For entities that compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process.	
			26.	Is the C-PEC decontaminated, cleaned, and disinfected prior to use if not operated continuously?		
			27.	Is a sink available for handwashing?		
			28.	Are eyewash stations and/or other emergency or safety precautions readily available?		
			29.	Are water sources and drains located to prevent interference with required ISO classifications?		
			30.	Are water sources and drains at least 1 meter from the C-PEC?		
			31.	If compounding nonsterile and sterile HDs in the same room, is the nonsterile C-PEC sufficiently effective to allow the room to maintain ISO 7 classification throughout the nonsterile compounding activity?		
			32.	If the C-PECs used for sterile and nonsterile compounding are placed in the same room, are they placed at least 1 meter apart and is particle-generating activity not occurring when sterile compounding is in process?		
			33.	Does the facility follow <795> for nonsterile compounding?	**USP Chapter 800- 5.3.1 NONSTERILE COMPOUNDING** In addition to this chapter, nonsterile compounding must follow standards in Pharmaceutical Compounding—Nonsterile Preparations <795>. A C-PEC is not required if manipulations are limited to handling of final dosage	
			34.	Do C-PECs used for manipulation of nonsterile HDs have either		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				external ventilation or redundant–HEPA filters in series?	forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses. The C-PECs used for manipulation of nonsterile HDs must be either externally vented (preferred) or have redundant–HEPA filters in series. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC used only for nonsterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified. The C-PEC must be placed in a C-SEC that has at least 12 ACPH. Table 2 summarizes the engineering controls required for nonsterile HD compounding. Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.	
			35.	Is nonsterile HD compounding performed in a C-PEC that provides personnel and environmental protection? ****A Class I Biological Safety Cabinet (BSC), Containment Ventilated Enclosure (CVE), Class II BSC, or a compounding aseptic containment isolator (CACI) may be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding is acceptable but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.****		
			36.	Is the C-PEC placed in a C-SEC that has at least 12 ACPH?		
			37.	Are surfaces in the nonsterile compounding area smooth, impervious, free from cracks and crevices, and non-shedding?		
			38.	Does the facility follow <797> for sterile compounding?	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING** In addition to this chapter, sterile compounding must follow standards in <797>. All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III BSC or CACI. Class II BSC types A2, B1, or B2 are acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile	
			39.	Are all C-PECs used for manipulation of sterile HDs externally vented?		
			40.	Do C-PECs maintain ISO Class 5 or better air quality?		
			41.	Is an LAFW or CAI not used for compounding of an antineoplastic HD?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			42.		Are non-HD preparations placed in a protective outer wrapper during removal from the C-PEC and labeled to require PPE handling precautions if prepared in a BSC or CACI?	components. *Appendix 3* describes the different types of BSCs. A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions. The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited as described in <797> for CSPs prepared in a segregated compounding area. *Table 3* summarizes the engineering controls required for sterile HD compounding.	
			43.		Is the C-PEC located in a C-SEC?		
			44.		Do BUDs of products compounded in a C-SCA follow <797>?		
			45.		If the negative-pressure buffer room is entered through the positive-pressure non-HD buffer room, are the following requirements met:	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING: ISO CLASS 7 BUFFER ROOM WITH AN ISO CLASS 7 ANTE-ROOM** The C-PEC is placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH. The buffer room must be externally vented. Because the room through which entry into the HD buffer room (e.g., ante-room or non-HD buffer room) plays an important role in terms of total contamination control, the following is required: • Minimum of 30 ACPH of HEPA-filtered supply air • Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas • Maintain an air quality of ISO Class 7 or better An ISO Class 7 ante-room with fixed walls is necessary to provide	
			45.	a	A line of demarcation is defined in the negative pressure buffer room for donning and doffing PPE		
			45.	b	A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure room is used that minimizes the spread of HD contamination		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			45.	c	A refrigerator pass-through is not used to transport HDs, HD CSPs, and HD waste in and out of the negative pressure buffer room	inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD. A hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room. Although not a recommended facility design, if the negative-pressure HD buffer room is entered through the positive-pressure non-HD buffer room, the following is also required: • A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE • A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must not be used. Other methods of containment (such as sealed containers) may be used. HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in <797>, based on the categories of CSP, sterility testing, and storage temperature.	
			46.		If the C-PEC is in an ISO 7 buffer room with an adjacent ISO 7 ante-room, are the following requirements met:		
			46.	a	The C-PEC is externally vented		
			46.	b	The C-SEC is externally vented		
			46.	c	The C-SEC has HEPA filtered air supply		
			46.	d	The C-SEC has a minimum of 30 ACPH		
			46.	e	The C-SEC maintains a negative pressure between 0.001 and 0.03 inches of water column		
			46.	f	The C-SEC maintains an air quality of ISO Class 7 or better		
			46.	g	A hand-washing sink is located in the ante-room and is located at least 1 meter from the entrance into the HD buffer room		
			46.	h	Both the ante-room and C-SEC have fixed walls		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			47.		If the C-PEC is located in an ISO 7 ante-room, does the room through which entry is made into the HD buffer room, e.g., the ante-room or non-HD buffer room, meet the following requirements:		
			47.	a	Has a minimum of 30 ACPH of HEPA filtered supply air		
			47.	b	Maintains a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas		
			47.	c	Maintains an air quality of ISO Class 7 or better		
			48.		Does the C-SCA meet the following:	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING: CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)** The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum of 12 ACPH. The C-SCA must be externally vented. A hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA. Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs prepared in the C-SCA must not exceed the BUDs described in <797> for CSPs prepared in a segregated compounding area.	
			48.	a	Fixed walls		
			48.	b	Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas		
			48.	c	Minimum of 12 ACPH		
			48.	d	Externally vented		
			48.	e	Hand-washing sink is placed at least 1 meter from C-PEC ****The sink may be located inside the C-SCA or directly outside the C-SCA.****		
			49.		Are only low- and medium-risk HD CSPs prepared in the C-SCA?		
			50.		Do HD CSPs comply with the BUDs in <797> for CSPs prepared in a SCA?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			51.	Are CSTDs used when administering antineoplastics?	**USP Chapter 800- 5.4 CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS** CSTDs must be used when administering antineoplastic HDs when the dosage form allows. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.	
Personal Protective Equipment						
			52.	Is disposable PPE discarded after a single use?	**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.	
			53.	Is reusable PPE decontaminated and cleaned after use?		
			54.	Is appropriate PPE worn during handling of HDs when receiving, storing, transporting, compounding, cleaning and disinfecting, administering, spill control, and waste disposal?	**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Two pairs of chemotherapy gloves are required for administering injectable antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs. For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see Types of Exposure) and activities performed. Appropriate PPE must be worn when handling HDs including during: receipt; storage; transport; compounding (sterile and nonsterile); administration deactivation/decontamination, cleaning, and disinfecting; spill control; waste disposal.	
			55.	If chemotherapy gloves are used, do they meet the following:	**USP Chapter 800- 7.1 GLOVES** When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs. Chemotherapy gloves must be powder-free because	
			55.	a ASTM standard D6978		
			55.	b Powder-free		
			55.	c Inspected for defects before use		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			55.	d	Sterile outer gloves used when sterile compounding	powder can contaminate the work area and can adsorb and retain HDs. Gloves must be inspected for physical defects before use. Do not use gloves with pin holes or weak spots. When used for sterile compounding, the outer chemotherapy gloves must be sterile. Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Hands must be washed with soap and water after removing gloves.	
			55.	e	Changed every 30 minutes unless otherwise recommended by the manufacturer's documentation		
			55.	f	Changed when torn, punctured, or contaminated		
			56.		Are hands washed with soap and water after removing gloves?		
			57.		Do gowns meet the following requirements:	**USP Chapter 800- 7.2 GOWNS** When gowns are required, they must be disposable and shown to resist permeability by HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact and may transfer to other healthcare workers or various surfaces. Washing on non-disposable clothing contaminated with HD residue should only be done according to facility policy as drug residue may be transferred to other clothing. Potentially contaminated clothing must not be taken home under any circumstances. Gowns must be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must	
			57.	a	Disposable		
			57.	b	Resist permeability by HDs		
			57.	c	Close in the back		
			57.	d	Long sleeved		
			57.	e	Closed cuffs that are elastic or knit		
			57.	f	Does not have seams or closures that could allow HDs to pass through		
			58.		Is potentially contaminated clothing not taken home under any circumstances?		
			59.		Are gowns changed per the manufacturer's information for permeation of the gown? ****If no permeation information is available for the gowns used, changing them every 2–3 hours or immediately after a spill or splash is acceptable.****		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			60.	Are gowns only worn in the HD handling areas?	not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.	
			61.	Is a second pair of shoe covers donned prior to entering the C-SEC and doffed upon exiting the C-SEC?	**USP Chapter 800- 7.3 HEAD, HAIR, SHOE, AND SLEEVE COVERS** When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.	
			62.	Is eye and face protection worn when there is a risk of a spill or splash?	**USP Chapter 800- 7.4 EYE AND FACE PROTECTION** Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). A full-face piece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.	
			63.	If required, is appropriate respiratory protection provided and used?	**USP Chapter 800- 7.5 RESPIRATORY PROTECTION** Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required.	
			64.	Is PPE placed into an appropriate waste container and disposed of per local, state, and federal regulations?	**USP Chapter 800- 7.6 DISPOSAL OF USED PERSONAL PROTECTIVE EQUIPMENT** Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			65.		Are chemotherapy gloves and sleeve covers carefully removed and discarded immediately into an approved waste container? ****Trace contaminated waste must be disposed inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.****	PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	
Hazard Communication Program							
			66.		Does the entity have established policies and procedures that ensure worker safety during HD handling?	**USP Chapter 800- 8 HAZARD COMMUNICATION PROGRAM** Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Elements of the hazard communication program plan must include: a written plan that describes how the standard will be implemented; all containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings; entities must have an SDS for each hazardous chemical they use (29 CFR 1910.1200); entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas; personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes; personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs.	
			67.		Does the entity have HD SOPs for the following:		
			67.	a	Labeling		
			67.	b	Transport		
			67.	c	Storage		
			67.	d	Disposal		
			67.	e	Use of Safety Data Sheets (SDS)		
			68.		Does the hazard communication program plan include the following:		
			68.	a	A written plan describing how the standard will be implemented		
			68.	b	Labeling, tagging, or marking of hazardous chemical containers that identify the material and include appropriate hazard warnings		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			68.	c	SDSs for each hazardous chemical used are readily available to personnel		
			68.	d	Information and training for personnel before initial assignment to work with a hazardous chemical and whenever the hazard changes		
			68.	e	Written confirmation from personnel of reproductive capability understanding the risks of handling HDs		
Personnel Training							
			69.		Are all personnel who handle HDs trained for their job functions?	**USP Chapter 800- 9 PERSONNEL TRAINING** All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented. The training must include at least the following: overview of entity's list of HDs and their risks; review of the entity's SOPs related to handling of HDs; proper use of PPE; proper use of equipment and devices (e.g., engineering controls); response to known or suspected HD exposure; spill management; proper disposal of HDs and trace-contaminated materials.	
			70.		Does training occur before the employee independently handles HDs?		
			71.		Is effectiveness of training demonstrated by each employee?		
			72.		Is personnel competency reassessed at least every 12 months?		
			73.		Are personnel trained prior to the following:		
			73.	a	Introduction of a new HD		
			73.	b	Introduction of new equipment		
			73.	c	New or significant change in process or SOP		
			74.		Are all training and competency assessments documented?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			75.	Does the training include the following:			
			75.	a	Overview of entity's list of HDs and their risks		
			75.	b	Review of the entity's SOPs related to handling of HDs		
			75.	c	Proper use of PPE		
			75.	d	Proper use of equipment and devices		
			75.	e	Response to known or suspected HD exposure		
			75.	f	Spill management		
			75.	g	Proper disposal of HDs and trace-contaminated materials		
Receiving							
			76.	Does the entity establish SOPs for receiving HDs?		**USP Chapter 800- 10 RECEIVING** The entity must establish SOPs for receiving HDs. HDs must be delivered to the HD storage area immediately after unpacking. PPE, including chemotherapy gloves, must be worn when unpacking HDs (see Personal Protective Equipment). A spill kit must be accessible in the receiving area. The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass). When opening damaged shipping containers, they should preferably be transported to a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile compounding is the only one available, it must be disinfected after the decontamination, deactivation, and cleaning step before returning to any sterile compounding	
			77.	Are HDs delivered to the HD storage area immediately after unpacking?			
			78.	Is PPE worn when unpacking HDs?			
			79.	Is a spill kit accessible in the receiving area?			
			80.	Does the entity enforce policies regarding HD receiving?			
			81.	If a sterile compounding C-PEC is used when opening damaged shipping containers, is it disinfected after decontamination, deactivation, and cleaning before			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				returning to sterile compounding activity?		activity. Damaged packages or shipping cartons must be considered spills that must be reported to the designated person and managed according to the entity's SOPs. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Clean-up must comply with established SOPs.	
			82.	Are damaged packages or shipping cartons:			
			82.	a	Considered spills		
			82.	b	Reported to the designated person		
			82.	c	Managed according to the entity's SOPs		
			82.	Does clean-up comply with established SOPs?			
Labeling, Packaging, Transport and Disposal							
			83.	Does the entity have SOPs for HD:		**USP Chapter 800- 11 LABELING, PACKAGING, TRANSPORT AND DISPOSAL** The entity must establish SOPs for the labeling, packaging, transport, and disposal of HDs. The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit.	
			83.	a	Labeling		
			83.	b	Packaging		
			83.	c	Transporting		
			83.	d	Disposal		
			84.	Are HDs labeled to include special handling precautions during transport?		**USP Chapter 800- 11.1 LABELING** HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport. Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.	
			85.	Do labeling processes prevent introduction of contamination in non-HD handling areas?			
			86.	Does packaging maintain physical integrity, stability, and sterility during transport?		**USP Chapter 800- 11.2 PACKAGING** Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The	
			87.	Does packaging protect the HD product from damage, leakage, contamination, and degradation during transport?			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			88.	Are there written SOPs for appropriate shipping containers and insulating materials?	entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.	
			89.	Are transported HDs labeled, stored, and handled in accordance with applicable regulations?	**USP Chapter 800- 11.3 TRANSPORT** HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. HDs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination. When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS. The entity must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.	
			90.	Are HDs transported in containers that minimize the risk of breakage or leakage?		
			91.	Does the entity not use pneumatic tubes to transport liquid or antineoplastic HDs?		
			92.	Does the entity consult the SDS when shipping HDs?		
			93.	Does the entity's HD labeling include storage, disposal, and HD category information consistent with the carrier's policies?		
			94.	Are personnel trained to properly dispose of HDs?	**USP Chapter 800- 11.4 DISPOSAL** All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination. Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.	
			95.	Does HD disposal comply with all applicable regulations?		
Dispensing Final Dosage Forms						
			96.	Is counting or repackaging of HDs done carefully?	**USP Chapter 800- 12. DISPENSING FINAL DOSAGE FORMS**	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			97.	~~The facility does not place antineoplastic HDs in automated counting or packaging machines.~~Does the facility prohibit placement of antineoplastic HDs in counting or packaging machines?~~-~~	Counting or repackaging of HDs must be done carefully. Clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.	
Compounding						
			98.	Are the entity and personnel compliant with USP <795> and/or <797>?	**USP Chapter 800- 13 COMPOUNDING** Entities and personnel involved in compounding HDs must be compliant with the appropriate USP standards for compounding including <795> and <797>. Compounding must be done in proper engineering controls as described in Compounding. When compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use, and should be discarded at the end of the daily compounding activity. Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs. Bulk containers of liquid and API HD must be handled carefully to avoid spills. If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).	
			99.	Is compounding performed in proper engineering controls?		
			100.	Does the entity have equipment dedicated to HD compounding?		
			101.	Are bulk containers of liquid and API HD handled carefully to avoid spills?		
			102.	Are APIs and powdered HDs handled in a C-PEC to protect against occupational exposure?		
Are HDs administered at the facility? If yes, continue to question 103. If no, skip to question 110.						
Administering ***This section applies to pharmacy personnel only (per Page 1 of the worksheet).***						
			103.	Are HDs administered safely using protective medical devices and techniques?	**USP Chapter 800- 14 ADMINISTERING** HDs must be administered safely using protective medical devices and techniques. Appropriate PPE must be worn	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			104.	Is appropriate PPE worn when administering HDs?	when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration. Equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration. CSTDs must be used for administration of antineoplastic HDs when the dosage form allows. Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes.	
			105.	Is PPE removed and disposed of in an approved HD waste container at the site of drug administration?		
			106.	Are equipment and packaging materials disposed of properly after administration?		
			107.	Are CSTDs used for administration of antineoplastic HDs when the dosage form allows?		
			108.	Are techniques and ancillary devices that minimize risk from open systems used when administering HDs through certain routes?		
			109.	Do personnel don appropriate PPE and use a plastic pouch for HD manipulation?	**USP Chapter 800- 14 ADMINISTERING** If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles generated.	
Deactivating, Decontaminating, Cleaning, and Disinfecting						
			110.	Are HD areas, equipment, and devices deactivated, decontaminated, and cleaned?	**USP Chapter 800- 15 DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING** All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected. The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Additionally, cleaning of nonsterile compounding areas must comply	
			111.	Are sterile compounding areas and devices disinfected after cleaning?		
			112.	Does the entity have written procedures for decontamination, deactivation, cleaning, and sterile compounding area disinfection?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			113.	Does cleaning of nonsterile compounding areas comply with <795> and cleaning of sterile compounding areas comply with <797>?	with <795> and cleaning of sterile compounding areas must comply with <797>. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements. All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination. All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns (see Personal Protective Equipment). Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used. The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials.	
			114.	Do written procedures for cleaning include procedures, agents used, dilutions (if used), frequency, and documentation requirements?		
			115.	Are personnel who perform deactivation, decontamination, cleaning, and disinfection in HD handling areas trained?		
			116.	Do personnel wear appropriate PPE?		
			117.	Are deactivating, decontaminating, cleaning, and disinfecting agents selected appropriate?		
			118.	Are products used compatible with surface material?	**USP Chapter 800- 15 DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING** The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. All disposable materials must be discarded to meet EPA regulations and the entity's policies. Perform cleaning in areas that are sufficiently ventilated.	
			119.	Does the disposal of materials meet EPA regulations and the entity's policies?		
			120.	Is the surface decontaminated after deactivation?	**USP Chapter 800- 15.1 DEACTIVATION** Residue from deactivation must be removed by decontaminating the surface… To prevent corrosion,	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			121.	Are products with known deactivation properties used whenever possible to deactivate residual HD compounds?	sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent).	
			122.	Do solutions used for wiping HD packaging not alter the product label?	**USP Chapter 800- 15.2 DECONTAMINATION** The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs. The C-PEC must be decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved. C-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the contamination level in the C-PEC.	
			123.	Are work surfaces of the C-PEC decontaminated between compounding different HDs?		
			124.	Is the C-PEC decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved?		
			125.	Are areas under the work tray deactivated, decontaminated, and cleaned at least monthly in the C-PEC?		
			126.	Are surfaces cleaned before disinfection?	**USP Chapter 800- 15.4 DISINFECTION** Before disinfection can be adequately performed, surfaces must be cleaned. Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.	
			127.	Are areas that are intended to be sterile disinfected?		
Spill Control						
			128.	Do personnel receive proper training in HD spill management, use of PPE, and NIOSH-certified respirators?	**USP Chapter 800- 16 SPILL CONTROL** All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators (see Personal Protective Equipment). Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel must be available at	
			129.	Are spills contained and cleaned immediately by qualified personnel with appropriate PPE?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			130.		Are qualified personnel available at all times while HDs are being handled?	all times while HDs are being handled. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled. If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available. All spill materials must be disposed of as hazardous waste. The circumstances and management of spills must be documented. SOPs must be developed to prevent spills and to direct the cleanup of HD spills. SOPs must address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required. The management of the spill (e.g., decontamination, deactivation, and cleaning) may be dependent on the size and type of spill. The SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit.	
			131.		Are signs available for restricting access to the spill area?		
			132.		Are spill kits readily available in all areas where HDs are routinely handled?		
			133.		If HDs are being prepared or administered in a non-routine healthcare area, is a spill kit and respirator available?		
			134.		Are spill materials disposed of as hazardous waste?		
			135.		Are the circumstances and management of spills documented?		
			136.		Do HD SOPs include the following:		
			136.	a	Spill prevention		
			136.	b	Direct the cleanup of spills		
			136.	c	Address the size and scope of the spill		
			136.	d	Specify who is responsible for spill management		
			136.	e	Type of PPE required		
			136.	f	Address the location of spill kits and clean-up materials		
			136.	g	Capacity of the spill kit		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Documentation and Standard Operating Procedures						
			137.	Does the entity have SOPs for the safe handling of HDs?	**USP Chapter 800- 17 DOCUMENTATION AND STANDARD OPERATING PROCEDURES** The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility. The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.	
			138.	Are the SOPs reviewed at least every 12 months by the designated person?		
			139.	Is the SOP review documented?		
			140.	Are revisions in forms or records made as needed and communicated to all personnel handling HDs?		
			141.	Is training documented for all personnel who handle HDs according to OSHA standards and applicable regulations?	**USP Chapter 800- 17 DOCUMENTATION AND STANDARD OPERATING PROCEDURES** Personnel who transport, compound, or administer HDs must document their training according to OSHA standards (see OSHA Standard 1910.120 Hazardous Waste Operations and Emergency Response) and other applicable laws and regulations.	

WA Pharmacy Quality Assurance Commission
~~2022~~ 2023 Responsible Pharmacy Manager
Pharmacy Self-Inspection Worksheet

USP 825 – Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging Addendum

ATTENTION: Responsible Pharmacy Manager or Equivalent

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March ~~or~~ and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy or ~~Equivalent~~ Hospital Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace **U.S. Pharmacopeia (USP) <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.** (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

This self-inspection worksheet applies only to activities performed by pharmacy personnel. Other healthcare professionals are regulated by their own boards and commissions.

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible pharmacy manager: _____

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
General Rule Reference - Applies to all questions throughout the worksheet. RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."						
INTRODUCTION						
			1.	Do prepared or compounded nonsterile preparations comply with applicable identity, quality, and purity standards?	**USP Chapter 825 – 1.1 Nonsterile Radiopharmaceuticals** For prepared or compounded preparations, such preparations must comply with applicable identity, quality, and purity standards, as described in manufacturer labeling, USP monographs, or other appropriate sources.	
			2.	Do prepared or compounded sterile preparations comply with applicable identity, quality, and purity standards?	**USP Chapter 825 – 1.2 Sterile Radiopharmaceuticals** Examples of sterile radiopharmaceuticals include injectables (e.g., intravenous, intrathecal, intraperitoneal, subcutaneous, and intradermal), inhalations, ophthalmics, and intra-organ instillations. For conventionally marketed products, see 12. Dispensing. For prepared or compounded preparations, such preparations must comply with applicable identity, quality, and purity standards. For compounded preparations involving one or more nonsterile components, a sterilization procedure (e.g., filtration with bubble point testing) must be performed prior to dispensing. For injectable compounded preparations involving one or more components that are not certified to be pyrogen-free, bacterial endotoxin testing, as defined in Bacterial Endotoxins Test <85>, must be performed prior to dispensing. The most important factor for maintaining sterility is the avoidance of touch contamination. Wipe the vial septum with sterile 70% isopropyl alcohol (IPA) prior to initial needle puncture. If the vial shield top is then closed, the septum must be disinfected again with sterile 70% IPA prior to another needle puncture. Some vial shields are constructed such that the vial septum is	
			3.	If nonsterile components are used for sterile compounded preparations, is sterilization performed prior to dispensing?		
			4.	If non-pyrogen-free components are used for sterile compounded preparations, is bacterial endotoxin testing performed prior to dispensing?		
			5.	Are vial septa wiped with sterile 70% isopropyl alcohol prior to initial needle puncture?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						recessed and difficult to access. One approach for disinfecting the vial septum in this type of vial shield is to use right-angle forceps to hold a sterile 70% IPA wipe and apply direct contact with the vial septum. It is also acknowledged that such vial shields disrupt first air contacting the vial septum during certain handling conditions. Wipe the septum with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose container).	
RADIATION SAFETY CONSIDERATIONS							
			6.	Are aseptic handling practices balanced with radiation safety considerations, based on the following:		**USP Chapter 825– 2 RADIATION SAFETY CONSIDERATIONS** The handling of radiopharmaceuticals necessitates meeting the radiation regulatory agency requirements for worker safety. This involves licensing commitments to keep all exposure levels for the workers involved as low as reasonably achievable (ALARA) practices. Principles of radiation safety involve time, distance, shielding, and contamination control. Moreover, radiation detection and measuring devices are necessary. Aseptic handling practices must be balanced with radiation safety considerations, based on the following: Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions; The quantity of radioactivity, volume, handling steps, and timing; Other factors, which can vary on a case-by-case basis.	
			6.	a	Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions		
			6.	b	The quantity of radioactivity, volume, handling steps, and timing		
			6.	c	Other factors, which can vary on a case-by-case basis		
			7.	If used, are disposable absorbent pads clean and low-lint?		**USP Chapter 825– 2.4 Radiation Contamination Control** RAM contamination (e.g., spills, drips, sprays, volatility) is an important concern for radiation protection. Therefore, various techniques and materials may be used by handlers of radiopharmaceuticals to minimize radioactive contaminations.	
			8.	Are policies implemented for handling biohazardous radioactive sharps while minimizing contamination?			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					For example, container contents are maintained at neutral or negative pressure, because positive pressure in a container is a common cause of radioactive contamination. Disposable absorbent pads are commonly used to contain such radioactive contamination and, when used in an ISO Class 5 PEC, the pads must be clean and low-lint. Vertical air flow, not horizontal, in a PEC is used to control contamination. When exposure to blood and other potentially infectious material is reasonably anticipated, some engineered needlestick prevention devices may pose a radiation hazard to employees. Policies must be implemented for handling biohazardous radioactive sharps while minimizing contamination.	
			9.	Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?	**USP Chapter 825– 2.4 Radiation Contamination Control- RADIATION DETECTORS AND MEASURING DEVICES** Radiopharmaceuticals require measurement with a suitable radiation measuring device (e.g., dose calibrator). These and other necessary equipment, (e.g., monitors, bar code scanner, label printer) may be placed inside an ISO Class 5 PEC but should be placed in a manner that minimizes disruptions of airflow. As per RAM license requirements, individuals must wear body and, as required, extremity dosimeters (e.g., a ring worn on a finger) for long-term monitoring of personnel radiation exposure. The body dosimeter should be worn underneath the gown. Any extremity dosimeter must be worn underneath gloves and must not interfere with proper fit of gloves.	
			10.	Are extremity dosimeters worn underneath gloves that do not interfere with proper fit of gloves?		
IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS						
			11.	When preparing radiopharmaceuticals under immediate use practice in an ambient environment that lacks	**USP Chapter 825– 3 IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS** The preparation and dispensing of sterile radiopharmaceuticals in a patient care setting may be	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				primary and secondary engineering controls when intended for a single patient, are the following met:		handled as an immediate use practice. The information below describes the appropriate handling requirements for immediate use sterile radiopharmaceuticals in an ambient environment that lacks primary and secondary engineering controls (SEC) when intended for a single patient. Strict aseptic technique and limited beyond-use date (BUD) must be adhered to given the lack of engineering controls. Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient; Preparation (including preparations with minor deviations) components must be sterile, conventionally manufactured drug products (e.g., NDA, ANDA); Dispensing of drug products produced under an approved IND or RDRC protocol is allowed; Manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) is allowed; Must be administered within 1 hour of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first; All components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first. Dose pooling (combining doses from two or more syringes to meet one patient's need) may be performed as immediate use. Any residual activity that remains must be immediately discarded and not utilized for any other patient; Follow hand hygiene and garbing in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations; Follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling. Follow 12.2 Labeling for labeling; Area for	
			11.	a	Strict aseptic technique and limited beyond-use date must be adhered to given the lack of engineering controls.		
			11.	b	Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient.		
			11.	c	Preparation (including preparations with minor deviations) components must be sterile, conventionally manufactured drug products.		
			11.	d	Dispensing of drug products produced under an approved IND or RDRC protocol is allowed.		
			11.	e	Manipulations for any unit doses or dispensing for one patient is allowed.		
			11.	f	Must be administered within 1 hour of the first container puncture or exposure of any critical site involved to ambient air, whichever is first.		
			11.	g	All components involved must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first.		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			11.	h	Dose pooling may be performed as immediate use. Any residual activity that remains must be immediately discarded and not utilized for any other patient.	sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area (e.g., radiolabeling food) during the time of use; Does not require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC. The number of steps or punctures is not limited; Does not require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (e.g., aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing); While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (e.g., lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to. Dose splitting (splitting a unit dose for administration to more than one patient) may not be performed as immediate use; if performed, dose splitting must be done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area.	
			11.	i	Follow hand hygiene and garbing in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations.		
			11.	j	Follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling.		
			11.	k	Follow 12.2 Labeling for labeling.		
			11.	l	Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area during the time of use.		
			11.	m	Does not require a segregated radiopharmaceutical processing area, classified area, or PEC.		
			11.	n	The number of steps or punctures is not limited.		
			11.	o	Does not require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications.		
			11.	p	While adding a non-radioactive, sterile and commercially manufactured pharmaceutical to a unit dose is otherwise considered compounding, it is		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					allowed for immediate use purposes as long as all of the above are adhered to.		
			11.	q	Dose splitting may not be performed as immediate use; if performed, dose splitting must be done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area.		
PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE							
			12.		Are personnel trained to work with radiopharmaceuticals per the policies and SOPs authorized by an ANP or AU physician?	**USP Chapter 825– 4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE** Personnel must be trained to work with radiopharmaceuticals per the policies and standard operating procedures (SOPs) authorized by an ANP or AU physician. These individuals (e.g., nuclear medicine technologists or nuclear pharmacy technicians) must follow these policies and SOPs of the ANP or AU physician and work under their supervision. As appropriate, this should include blood-borne pathogens training. Individuals entering a compounding area must be properly garbed and must maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals. Individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (e.g., rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) must report these conditions to their supervisor. The designated person is responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved.	
			13.		Do personnel follow the policies and SOPs of the ANP or AU physician?		
			14.		Do personnel work under the supervision of the ANP or AU physician?		
			15.		Are individuals entering the compounding area properly garbed?		
			16.		Are individuals maintaining proper personal hygiene?		
			17.		Do individuals who have a condition that may pose a higher potential of contamination with microorganisms report these conditions to their supervisor?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			18.		Do personnel prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use?	**USP Chapter 825– 4.1 Aseptic Qualifications** Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use. These qualifications may be conducted at a different site if all SOPs are identical for the applicable job function. These qualifications must be completed and documented initially, and then successfully repeated at intervals described below in Timing of Reevaluation and Requalification under the observation of a designated person and include the following: Aseptic technique training with a documented assessment (written or electronic); Garbing and hand hygiene, as defined by the policies and SOPs; PEC cleaning and disinfecting; Gloved fingertip and thumb sampling; Media-fill testing.	
			19.		Are these qualifications completed and documented initially?		
			20.		Are these qualifications completed and documented at repeated intervals?		
			21.		Are these qualifications completed and documented under the observation of a designated person?		
			22.		Do the qualifications include the following:		
			22.	a	Aseptic technique training with a documented assessment		
			22.	b	Garbing and hand hygiene, as defined by the policies and SOPs		
			22.	c	PEC cleaning and disinfecting		
			22.	d	Gloved fingertip and thumb sampling		
			22.	e	Media-fill testing		
			23.		Do personnel that perform tasks in an ISO Class 5 PEC prove their competency in appropriate garbing?	**USP Chapter 825– 4.1 Aseptic Qualifications - GLOVED FINGERTIP AND THUMB SAMPLING** Appropriate garbing, including sterile gloves, is necessary for personnel who enter and perform tasks in an ISO Class 5 PEC (e.g., aseptic manipulations, cleaning the PEC). Personnel that perform such functions must prove their competency in this process. Gloved fingertip and thumb sampling must be performed initially on	
			24.		Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			25.		Do touch plates or other devices contain general microbial growth agar supplemented with neutralizing additives?	both hands, immediately following hand hygiene and garbing. Successful completion of initial gloved fingertip and thumb sampling is defined as zero colony-forming unis (cfu) and subsequent gloved fingertip and thumb sampling after media-fill testing is defined as ≤3 cfu (total for both hands). The gloved fingertip and thumb sampling must be performed with touch plates or other devices (e.g., plates, paddles, or slides) that contain a general microbial growth agar [e.g., trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this supports both bacterial and fungal growth; Gloves must not be disinfected immediately before touching the sampling device, as this could cause a false-negative result; Using a separate sampling device for each hand, a gloved fingertip and thumb sample from both hands must be collected by rolling finger pads and thumb pad over the agar surface; The plates must be incubated in an incubator at 30°–35° for no less than 48 h, and then at 20°–25° for no less than 5 additional days.	
			26.		Are gloves not disinfected immediately before touching the sampling device?		
			27.		Are gloved fingertip and thumb samples from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?		
			28.		Are plates incubated in an incubator at 30°–35° for no less than 48 hours and then at 20°–25° for no less than 5 additional days?		
			29.		Is media-fill testing reflective of actual manipulations carried out by the individual?	**USP Chapter 825– 4.1 Aseptic Qualifications - MEDIA-FILL TESTING** Media-fill testing is necessary for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals. This testing must be reflective of the actual manipulations to be carried out by the individual and must simulate the most challenging and stressful conditions to be encountered in the worker's duties. Media-fill tests must be documented as defined by the facility's policies and SOPs. Media-fill tests should be performed at the end of a work session in the PEC. Media-fill tests must be performed with a commercial source of soybean–casein digest medium.	
			30.		Does media-fill testing simulate the most challenging and stressful conditions encountered in the worker's duties?		
			31.		Does media-fill testing meet the following:		
			31.	a	~~Documented~~ Are media-fill tests documented as defined by the facility's policies and SOPs?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			31.	b	Performed with a commercial source of soybean–casein digest medium	Those performing sterile-to-sterile processing activities must start with sterile media. Those performing nonsterile-to-sterile compounding must use a nonsterile soybean–casein digest powder to make a solution. Dissolve nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation. The certificate of analysis (CoA) must include documentation of growth promotion testing for each lot of media used. Once the media-fill simulation is completed and the final containers are filled with the test medium, incubate media-filled containers in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms. Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days. In the event of failure, results of the evaluation and corrective actions must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, and the results.	
			31.	c	For sterile-to-sterile processing, activities start with sterile media		
			31.	d	For nonsterile-to-sterile compounding, use a nonsterile soybean–casein digest powder to make a solution		
			32.		Does the certificate of analysis include documentation of growth promotion testing for each lot of media used?		
			33.		In the event of failure, are results of the evaluation and corrective actions documented?		
			34.		Is the documentation maintained to provide a record and long-term assessment of personnel competency?		
			35.		Does documentation meet the following:		
			35.	a	Name of the person evaluated		
			35.	b	Evaluation date/time		
			35.	c	Media and components used including manufacturer		
			35.	d	Expiration date and lot number		
			35.	e	Starting temperature for each interval of incubation		
			35.	f	Dates of incubation		
			35.	g	Results		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			36.	Do personnel successfully pass reevaluations in deficient area(s) before they can resume processing of sterile preparations?	**USP Chapter 825– 4.2 Reevaluation, Retraining, and Requalification - REQUALIFICATION AFTER FAILURE** Personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing must successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile preparations. All failures, retraining, and reevaluations must be documented.	
			37.	Are all failures, retraining, and reevaluations documented?		
			38.	Do personnel successfully complete requalification in the core competencies?	**USP Chapter 825– 4.2 Reevaluation, Retraining, and Requalification - REQUALIFICATION PROGRAM** Personnel must successfully complete requalification in the core competencies listed in 4.1 Aseptic Qualifications. Successful completion must be demonstrated through observation, written testing, and hands-on demonstration of skills.	
			39.	Is successful completion demonstrated through observation, written testing, and hands-on demonstration of skills?		
			40.	Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures initially, and then at least once every 12 months?	**USP Chapter 825– 4.2 Reevaluation, Retraining, and Requalification - TIMING OF REEVALUATION AND REQUALIFICATION** Visual observation: Personnel must be visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures initially, and then at least once every 12 months. Gloved fingertip and thumb sampling: Personnel must perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing). Media-fill testing: After initial qualification, conduct a media-fill test of all personnel engaged in sterile radiopharmaceutical processing at least every 12 months (in conjunction with gloved fingertip and thumb sampling). Cleaning and disinfecting: Retrain and requalify personnel in the	
			41.	Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months?		
			42.	Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			43.		Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?	cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner. After a pause in sterile radiopharmaceutical processing: Personnel that have not performed radiopharmaceutical processing in more than 6 months must be requalified in all core competencies before resuming duties. Sterile compounding using a nonsterile drug substance or components: Personnel who perform sterile compounding using a nonsterile drug substance or components (see 11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components) must be requalified in all core competencies every 6 months.	
			44.		Do other personnel or visitors comply with garbing and gloving SOPs? ****These individuals do not need to prove competency.****	**USP Chapter 825– 4.3 Ancillary Personnel** Personnel who are authorized to be within the sterile processing area and do not handle sterile preparations are not required to complete training on media-fill testing but are required to complete all other training and testing. Other personnel or visitors (e.g., auditors, regulators, student observers) must comply with garbing and gloving SOPs but do not need to prove competency.	
			45.		For immediate use preparations, do precautions related to personal hygiene include the following:	**USP Chapter 825– 4.4 Hand Hygiene and Garbing for Immediate Use Preparations** Radiopharmaceuticals may be prepared and dispensed as immediate use, and the precautions related to personal hygiene to be followed must include the following: Hand hygiene: Wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands. Garbing: Immediately after hand hygiene, don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with	
			45.	a	Hand hygiene		
			45.	b	Garbing		
			45.	c	Different lab coat worn for patient care than preparation		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						sterile 70% IPA. [NOTE—A different lab coat must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation.]	
			46.	For activities in an ISO Class 5 PEC, precautions related to personal hygiene include the following:		**USP Chapter 825– 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area** In situations involving repackaging, dispensing, preparation, preparation with minor deviations, or compounding of sterile radiopharmaceuticals in an ISO Class 5 PEC, the following precautions related to personal hygiene are to be followed: Before entering the SRPA or buffer area, personnel must remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); all cosmetics; all hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection). Nail products (e.g., artificial nails, polish, extenders) are prohibited. Natural nails must be kept neat and trimmed. Remove ear buds and headphones. Radiation dosimetry devices are allowed, as required by the RAM license. Do not bring electronic devices that are not necessary for compounding or other required tasks. Immediately before entering the SRPA or buffer area, remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner. Personnel must wash hands and arms up the elbows with soap and water for at least 30 s and then dry hands using low-lint towels. Alternatively, hand washing may be performed after donning shoe covers, head/hair covers, and face mask, as described below. Personnel must don the following garb—shoe covers, head/hair/facial hair covers, face mask—in an order that eliminates the greatest risk of contamination, as defined in facility SOPs. If not already performed, remove visible debris	
			46.	a	Remove outer garments, cosmetics, exposed jewelry, and piercings that could interfere with garbing		
			46.	b	Nail products prohibited		
			46.	c	Natural nails kept neat and trimmed		
			46.	d	Ear buds and headphones removed		
			46.	e	Wash hands and arms up the elbows with soap and water for at least 30 seconds		
			46.	f	Dry hands using low-lint towels		
			46.	g	Don shoe covers, head/hair/facial hair covers, and face mask		
			46.	h	Don a low-lint gown with sleeves that fit snugly around the wrists and enclosed at the neck		
			46.	i	Clean reusable gown donned daily		
			46.	j	Aseptically don sterile, powder-free gloves		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			46.	k	Gloves completely and snugly cover the ends of the gown cuffs	from underneath fingernails under warm running water using a disposable nail cleaner. Personnel must then wash hands and arms up to the elbows with soap and water for at least 30 s and then dry hands using low-lint towels. Electronic hand dryers are not permitted. Personnel must then perform hand antisepsis cleansing using a suitable alcohol-based hand rub. Personnel must then don a low-lint gown with sleeves that fit snugly around the wrists and enclosed at the neck. Disposable gowns are preferred. If reusable gowns are used, a clean gown must be donned daily. Personnel must then aseptically don sterile, powder-free gloves. Gloves must completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped. Because gloves may not remain sterile due to touching or handling potentially nonsterile materials, personnel must periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination. Personnel must also routinely inspect the gloves that they are wearing for holes, punctures, radioactivity contamination, or tears. If a defect, radioactivity contamination, or malfunction is detected, personnel must immediately remove the gloves, repeat antiseptic hand cleansing using an alcohol-based hand rub, and don new sterile gloves. Direct personnel touch contamination is the most common source of microorganisms, so personnel must avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites. When personnel exit the buffer area or SRPA, shoe covers, head/hair covers, face masks, and gloves must be properly disposed of and new ones donned for each reentry into the buffer area or SRPA. Gowns may be re-used within the same shift if the gown is maintained in a classified area or in (or immediately outside of) the SRPA that minimizes contamination (e.g., away from sinks).	
			46.	l	Periodically apply sterile 70% IPA to gloves		
			46.	m	Routinely inspect the gloves for holes, punctures, radioactivity contamination, or tears		
			46.	n	Immediately remove gloves if defective, radioactivity contamination, or malfunction and repeat antiseptic hand cleansing		
			46.	o	Avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites		
			46.	p	Upon exit of the SPRA or buffer are ~~,~~ donned items are properly disposed of		
			46.	q	New items are donned for reentry into the buffer area or SRPA		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
FACILITIES AND ENGINEERING CONTROLS						
			47.	Are sterile radiopharmaceutical facilities designed and controlled to minimize airborne contamination provide a well-lighted as well as a comfortable working environment?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls** In addition to minimizing airborne contamination, sterile radiopharmaceutical facilities must be designed and controlled to provide a well-lighted and comfortable working environment (see Physical Environments That Promote Safe Medication Use <1066>). The classified areas and SRPA must be continuously maintained at a temperature of 25° or cooler and should be continuously maintained at a relative humidity (RH) below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for personnel attired in the required garb. The temperature and humidity must be monitored in the classified areas each day that it is used, either manually or by a continuous recording device. The results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device, and must be retrievable. The temperature and humidity readings must be reviewed as described in the facility's SOPs. Free-standing humidifiers/dehumidifiers and air conditioners must not be used within the classified area or SRPA. Temperature and humidity monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer. The designated person is responsible for ensuring that each area related to sterile radiopharmaceutical processes meets the classified air quality standard appropriate for the activities to be conducted in that area. They must also ensure that the ISO Class 5 PECs are located, operated,	
			48.	Are classified areas and SRPA continuously maintained at a temperature of 25° or cooler?		
			49.	Is temperature and humidity monitored in the classified areas each day that it is used? ****Either manually or by a continuous recording device is acceptable.****		
			50.	Are results of the temperature and humidity readings documented at least once daily or stored in the continuous recording device, and retrievable?		
			51.	Are documented results of the temperature and humidity readings retrievable?		
			52.	Are temperature and humidity readings reviewed as described in the facility's SOPs?		
			53.	Are free-standing humidifiers/dehumidifiers and air conditioners not used within the classified area or SRPA?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			54.	Are temperature and humidity monitoring devices verified for accuracy at least every 12 months or as required by the manufacturer?	maintained, monitored, and certified to have appropriate air quality.	
			55.	Does the designated person ensure that each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?		
			56.	Does the designated person ensure that ISO Class 5 PECs are located, operated, maintained, monitored, and certified to have appropriate air quality?		
			57.	Are tacky surfaces not used in ISO-classified areas?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls -TYPES OF SECONDARY ENGINEERING CONTROLS AND DESIGN** Due to the interdependence of the various areas or areas that make up a sterile radiopharmaceutical processing facility, it is essential to define and control the dynamic interactions permitted between areas. When designing doors, consider the placement of door closures, door surfaces, and the movement of the door, all of which can affect airflow. Tacky surfaces must not be used in ISO-classified areas. The PEC must be located in a SEC, which may be either an ISO-classified buffer room with ante-room or an SRPA, in a manner that minimizes conditions that could increase the risk of microbial contamination. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a	
			58.	Is the PEC located in a SEC in a manner that decreases the risk of microbial contamination? ****Either an ISO-classified buffer room with ante-room or an SRPA is acceptable.****		
			59.	Are ISO-classified ante-rooms and buffer areas separated from surrounding unclassified areas of the facility with fixed walls and doors?		
			60.	Are facility designs and controls in place to minimize flow of lower-quality air into more controlled areas?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			61.	Is air supplied to classified areas introduced through HEPA filters located in the ceiling?	laminar airflow workbench (LAFW) or biological safety cabinet (BSC). The ISO-classified ante-room and buffer area must be separated from the surrounding unclassified areas of the facility with fixed walls and doors. Facility design and controls must be in place to minimize the flow of lower-quality air into the more controlled areas. Air supplied to the classified areas must be introduced through HEPA filters that are located in the ceiling. Returns must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate. A smoke study of the PEC must be repeated whenever a change to the placement of the PEC within the area is made. The classified areas must be equipped with a pressure-differential monitoring system. The ante-room must have a line of demarcation to separate the clean side from the less clean side. The ante-room is entered through the less clean side, and the clean side is the area closest to the buffer area. Required garb must be worn prior to crossing the line of demarcation (see 4. Personnel Qualifications, Training, and Hygiene). A PEC may be located within an unclassified area, without an ante-room or buffer area. This type of design is called an SRPA. Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA. If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (e.g., Tc-99m). The SRPA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC. The impact of activities that will be conducted around or adjacent to the SRPA must be considered carefully when designing such an area. A visible perimeter must establish the	
			62.	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?		
			63.	Are smoke studies of the PEC repeated when a change to the placement of the PEC is made within the area?		
			64.	Are classified areas equipped with a pressure-differential monitoring system?		
			65.	Do ante-rooms have a line of demarcation to separate the clean side from the less clean side?		
			66.	Is required garb worn prior to crossing the line of demarcation?		
			67.	Is the SRPA located away from unsealed windows, doors that connect to the outdoors, and traffic flow?		
			68.	Is the impact of activities conducted around or adjacent to the SRPA considered when designing the area?		
			69.	Does a visible perimeter establish the boundaries of the SRPA?		
			70.	Is access to the SRPA restricted to authorized personnel and required materials?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			71.	Is the SRPA not located adjacent to environmental control challenges?	boundaries of the SRPA. Access to the SRPA must be restricted to authorized personnel and required materials. An SRPA must not be located adjacent to environmental control challenges. It is also critical to control materials (e.g., supplies and equipment) as they move from classified areas of lower quality to those of higher quality (e.g., ISO Class 8 ante-room to ISO Class 7 buffer area to ISO Class 5 PEC) to prevent the influx of contaminants. Airlocks and interlocking doors can be used to facilitate better control of air flow between areas of differing ISO classification (e.g., between the buffer area and ante-room), or between a classified area and an unclassified area (e.g., between the ante-room and an unclassified area such as a hallway) See 5.7 Environmental Controls for a description of air pressure differentials. If a pass-through is used, both doors must never be opened at the same time, which may be achieved using interlocking mechanisms.	
			72.	Are both pass-through doors never opened at the same time?		
			73.	Are PECs certified to meet ISO Class 5 or better conditions?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls – THE RADIOPHARMACEUTICAL PROCESSING ENVIRONMENT** The PEC must be certified to meet ISO Class 5 or better conditions (see Table 1) and must be designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic operating conditions. The airflow in the PEC must be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the “first air” at the face of the filter is, for the purpose of aseptic processing, free from airborne particulate contamination. HEPA-filtered air must be supplied in the direct processing area (DPA) (ISO Class 5; see Table 1) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during	
			74.	Are PECs designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic operating conditions?		
			75.	Is airflow in PECs unidirectional?		
			76.	Is HEPA-filtered air supplied in the direct processing area at a velocity sufficient to sweep particles away from aseptic processing areas?		
			77.	Does HEPA-filtered air maintain unidirectional airflow during operations?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			78.	Are smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?	operations, given the limitations added from the radiation shielding in the DPA. Proper design and control prevents turbulence and stagnant air in the DPA. In situ air pattern analysis via smoke studies must be conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions.	
			79.	Does placement of PECs allow for cleaning around the PECs?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls - TYPES OF PECS AND PLACEMENT** Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for preparing radiopharmaceuticals. Placement of the PEC must allow for cleaning around the PEC. PEC provides an ISO Class 5 or better environment for sterile radiopharmaceuticals. The unidirectional airflow within the PEC helps protect the DPA from process-generated contamination of an aseptic processing environment. The unidirectional airflow within the PEC helps protect the DPA from process-generated contamination (e.g., opening wrappings of sterile containers, worker movement, etc.) as well as from outside sources. Laminar airflow workbench (LAFW): An LAFW used for preparing radiopharmaceuticals must provide vertical unidirectional HEPA-filtered airflow. In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized. Biological safety cabinet (BSC) Class II: A BSC Class II is a cabinet with an open front, inward airflow, downward unidirectional HEPA-filtered airflow, and HEPA-filtered exhaust. The BSC is designed to provide worker protection from exposure to biohazardous material and to provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals. Placement of PEC: The PEC must be located out of traffic patterns and away from area	
			80.	Do LAFWs used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow? ****If LAFWs are located within the segregated containment area of a hot-cell, it is acceptable to have horizontal unidirectional HEPA-filtered airflow patterns.****		
			81.	Are PECs located out of traffic patterns and away from area air currents?		
			82.	If used to compound sterile radiopharmaceuticals, are PECs located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom? (Refer to Table 7)		
			83.	Are dynamic airflow smoke pattern tests performed initially and at least every 6 months?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					air currents that could disrupt the intended airflow patterns inside the PEC. If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA. If used to compound sterile radiopharmaceuticals, the PEC must be located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom. ***See also Table 7. Preparation Conditions for Sterile Radiopharmaceuticals on Page 70 of this worksheet.*** A dynamic airflow smoke pattern test must be performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA.	
			84.	Is a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls - AIR-EXCHANGE REQUIREMENTS** For classified areas, adequate HEPA-filtered airflow to the buffer area(s) and ante-room(s) is required to maintain the appropriate ISO classification during processing activities. Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). The ACPH may need to be higher to maintain the required ISO classification and microbial state of control depending on these factors: the number of personnel permitted to work in the area, the number of particulates that may be generated from activities and processes in the area, the equipment located in the area, the area pressure, and the effects of temperature. The summary of ACPH requirements is listed in Table 2. A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 areas. The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7	
			85.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 7 under dynamic operating conditions?		
			86.	Does at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
			87.	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?		
			88.	Are the ACPH from HVAC, ACPH from the PEC, and total ACPH		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				documented on certification reports?	under dynamic operating conditions considering factors listed above; At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling; The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH; If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance; The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on certification reports; A minimum of 20 ACPH of HEPA-filtered air must be supplied to ISO Class 8 areas; The total HEPA-filtered air change rate must be adequate to maintain ISO Class 8 under dynamic operating conditions considering factors listed above; At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling; Ante-rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions; The total ACPH must be documented on certification reports.	
			89.	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?		
			90.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 8 under dynamic operating conditions?		
			91.	Does at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
			92.	Is the total ACPH documented on certification reports?		
			93.	Are surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding?	**USP Chapter 825– 5.2 Creating Areas to Achieve Easily Cleanable Conditions - CLASSIFIED AREAS** The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate. Junctures between the ceiling and the walls and between the wall and the floor must be sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, each panel must be caulked or otherwise sealed and secured to seal them to the support frame. Surfaces	
			94.	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices?		
			95.	Is each inlaid ceiling panel caulked or otherwise sealed and secured?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			96.	Are walls constructed of or covered with a durable material?	should be resistant to damage by cleaning agents, disinfectants, and tools used to clean. Walls must be constructed of or covered with a durable material (e.g., epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface must be maintained. Panels must be joined together and sealed to each other and the support structure. Floors must include coving to the sidewall or the juncture between the floor and wall must be caulked. Floors must include coving to the sidewall. Classified areas should minimize dust-collecting overhangs such as utility pipes and ledges such as windowsills. If overhangs or ledges are present, they must be easily cleanable. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed.	
			97.	Are walls constructed of or covered so the integrity of the surface is maintained?		
			98.	Are panels joined together and sealed to each other and the support structure?		
			99.	Do floors include coving to the sidewall?		
			100.	Are junctures between the floor and walls caulked?		
			101.	Do floors include coving to the sidewall?		
			102.	Are overhangs or ledges easily cleanable?		
			103.	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?		
			104.	Are penetrations through the ceiling or walls sealed?		
			105.	Are SRPA and all surfaces within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	**USP Chapter 825– 5.2 Creating Areas to Achieve Easily Cleanable Conditions - SRPA** The SRPA and all surfaces (e.g., walls, floors, counters, equipment) within the SRPA must be clean, uncluttered, and dedicated to sterile	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			106.	Are overhangs or ledges easily cleanable?	radiopharmaceutical processing activities. Surfaces in the SRPA should be smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate. Surfaces should be resistant to damage by cleaning agents, disinfectants, and tools used to clean. Dust-collecting overhangs such as utility pipes and ledges such as windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable.	
			107.	Is the facility where sterile radiopharmaceuticals are prepared designed so that activities such as hand hygiene and garbing do not adversely affect the ability of the PEC to function as designed?	**USP Chapter 825– 5.3 Water Sources** The facility where sterile radiopharmaceuticals are prepared must be designed so that activities such as hand hygiene and garbing should not adversely affect the ability of the PEC to function as designed. Sinks should enable hands-free use with a closed system of soap (i.e., non-refillable) to minimize the risk of extrinsic contamination. In facilities with an ante-room and buffer area, the sink used for hand hygiene may be placed either inside or outside of the ante-room. If the sink is located outside of the ante-room, it must be located in a clean space to minimize the risk of bringing in contaminants into the anteroom. If the sink is located inside the ante-room, it may be placed on either the clean side or the less-clean side of the anteroom. [NOTE—The order of hand washing and garbing would depend on the placement of the sink (see 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area).] The buffer area must not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)]. The ante-room must not contain floor drain(s). If installed, sprinkler systems in classified areas should be recessed and covered, and should be easily cleanable. In a facility with an SRPA design, the sink must be accessible but located at least 1 m from the PEC and generators, if	
			108.	If the sink is located outside of the ante-room, is the sink located in a clean space to minimize the risk of bringing in contaminants into the anteroom?		
			109.	Does the buffer area not contain plumbed water sources?		
			110.	Does the ante-room not contain floor drains?		
			111.	In a facility with a SRPA design, is the sink accessible but located at least 1 m from the PEC and generators?		
			112.	Is the sink not located inside the perimeter of the SRPA?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					present. The sink must not be located inside the perimeter of the SRPA.	
			113.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation not adversely impact environmental air quality?	**USP Chapter 825– 5.4 Placement and Movement of Materials** Only furniture, equipment, and other materials necessary are permitted in the classified area or SRPA and they should be low-shedding and easily cleaned and disinfected. Their number, design, location, and manner of installation must not adversely impact environmental air quality and must promote effective cleaning and disinfecting. No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the classified area or SRPA. Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels. All items must be wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-through(s), into an SRPA or into an ISO 5 PEC. However, constraints that would lead to excessive radiation exposure to radiation for workers and thereby be contradictory to following ALARA safety principles (e.g., the wiping of unshielded sources of radioactive material) might preclude this from occurring. In a classified area, carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected.	
			114.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation promote effective cleaning and disinfecting?		
			115.	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?		
			116.	Are items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-rooms, pass-throughs, into an SRPA or into an ISO 5 PEC?		
			117.	Are carts cleaned and disinfected if they are moved from the clean side to the dirty side of the anteroom?		
			118.	Are activities and tasks carried out within the buffer area limited to only those necessary?	**USP Chapter 825– 5.5 Classified Areas** Activities and tasks carried out within the buffer area must be limited to only those necessary. Food, drinks, and materials exposed in patient care and treatment areas must not enter ante-rooms or buffer areas. When processing activities require the manipulation of blood-	
			119.	Are food, drinks, and materials kept out of patient care, treatment		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				areas, ante-rooms, and buffer areas if exposed in patient care and treatment areas?	derived or other biological material (e.g., radiolabeling patient's or donor's blood cells), the manipulations must be clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities, and they must be controlled by specific SOPs to avoid any cross-contamination.	
			120.	Are activities that require the manipulation of blood-derived or other biological material separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?		
			121.	Are activities that require the manipulation of blood-derived or other biological material separated from routine material-handling procedures and equipment controlled by specific SOPs to avoid cross-contamination?		
			122.	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements listed in 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area?	**USP Chapter 825– 5.6 Remote Aseptic Processing Involving a Hot-Cell** A hot-cell device provides an inherent physical segregation for the ISO Class 5 aseptic processing area. If the hot-cell is located in an ISO-classified space, personnel must garb according to requirements listed in 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area. In settings where tasks are carried out within the hot-cell enclosure not within an ISO-classified space by remote means (i.e., no direct intervention by personnel into the ISO Class 5 space), it is not necessary for personnel to don the garbing described in 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located. If hand and arm incursions into the interior of the hot-cell might be necessary for personnel to stage the required	
			123.	When the PEC is located within a hot-cell, do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area do not allow the influx of unclassified air into the PEC?		
			124.	When the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, do dynamic airflow smoke pattern		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?	materials and supplies, the personnel must garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship. For situations where a PEC device is located within a hot-cell, dynamic airflow smoke pattern tests must show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC. Personnel may be garbed in nonsterile gloves and a low-particulate lab coat for interventions that are outside of the PEC. A failure of the airflow smoke pattern test requires personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell. For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, dynamic airflow smoke pattern tests must show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC. Personnel may be garbed in nonsterile gloves and a low particulate lab coat for interventions that are outside of the PEC. A failure of the airflow smoke pattern test requires personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC. Since other hot-cell/PEC configurations and technologies may exist, verification (either by airflow smoke pattern tests or other manufacturer specified methods) must ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space. A failure of the airflow smoke pattern test requires personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell.	
			125.	Does verification by either airflow smoke pattern tests or other manufacturer specified methods ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			126.	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations?	**USP Chapter 825– 5.7 Environmental Controls** All RAM users must comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls described in this section. Passthrough enclosures for transferring radiopharmaceuticals from controlled handling areas (e.g., buffer area) should be designed to provide reasonable balance between maintenance of air quality and other worker safety concerns (e.g., radiation exposure, physical injury from lifting heavy shielded cases). At a minimum, there must be a mechanical system or SOP in place that ensures that both doors cannot be open at the same time. There may be both positive and negative air pressure within the facility; positive pressure to minimize the potential of microbial contamination in sterile drug preparation areas, and negative pressure to minimize potential radioactive contamination from volatile or airborne radiopharmaceuticals. Positive pressure environments must have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (e.g., between the buffer area and ante-room). The pressure differential between the ante-room and the unclassified area must be no less than a positive 0.02-inch water column. Refer to the RAM license for negative pressure requirements. For preparation of sterile radiopharmaceuticals, consideration of both concerns could be addressed as follows: 1. Buffer area, if present, must be positive pressure compared to the ante-room 2. Ante-room, if present, must be positive pressure compared to unclassified portions of the restricted area 3. Restricted area, in the presence of volatile or airborne radiopharmaceuticals, must be negative pressure compared to the unrestricted area 4. SRPA must be negative pressure compared to unrestricted	
			127.	Is there a mechanical system or SOP in place that ensures that both passthrough doors cannot be open at the same time?		
			128.	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area?		
			129.	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						areas in the presence of volatile or airborne radiopharmaceuticals (e.g., I-131 sodium iodide and Xenon). Various environmental controls for various preparation scenarios (see Table 7 for maximum BUDs for differing environments) are described in the following sections. Table 1 details the limits for particle counts for each specific ISO classification.	
			130.	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-rooms and buffer areas and between the ante-room and the general environment outside the classified areas?		**USP Chapter 825– 5.7 Environmental Controls - ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS** Any time a pressure differential is required, a pressure monitoring device is required. In a classified area, a pressure differential monitoring system must be used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante-room and the general environment outside the classified area(s) or area(s). The results from the pressure monitoring system must be reviewed and documented at least daily on days the area is used. All pressure monitoring devices must be tested for accuracy and required performance at least every 6 months.	
			131.	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?			
			132.	Are all pressure monitoring devices tested for accuracy and performance at least every 6 months?			
			133.	Do SRPAs with vertical ISO Class 5 PECs meet the following:		**USP Chapter 825– 5.7 Environmental Controls - SRPA WITH VERTICAL FLOW ISO CLASS 5 PEC(S) FOR RADIOPHARMACEUTICAL PREPARATIONS** An SRPA with vertical ISO Class 5 PECs must meet the following requirements: Area surrounding the PEC may be ambient (unclassified) atmosphere; Area must be clean, uncluttered, and dedicated to the processing of radiopharmaceuticals; Appropriate for preparation, preparation with minor deviations, repackaging, and	
			133.	a	Area surrounding the PEC may be ambient (unclassified) atmosphere		
			133.	b	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			133.	c	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals	dispensing of radiopharmaceuticals. An area that meets ISO Class 8 total airborne particle-count specifications may be used to store and elute non-direct infusion radionuclide generators (e.g., Tc-99m).	
			134.		Is certification of the classified areas, including PECs, performed initially and at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline?	**USP Chapter 825– 5.7 Environmental Controls - CERTIFICATION OF PECS AND ENVIRONMENT IN WHICH THE PEC IS LOCATED** Certification of the classified areas, including the PEC, must be performed initially and recertification must be performed at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline, and must include the following: Airflow testing: To determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions; HEPA filter integrity testing: HEPA filters must be leak tested after installation and as part of recertification; Total particle counts testing: Conducted under dynamic operating conditions using calibrated electronic equipment; Smoke visualization studies: Performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). In cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards, other equivalent means for certifying the PEC may be performed and documented per facility SOPs. In this case, the PEC must maintain the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.	
			135.		Does certification of the classified areas, including PECs, include the following:		
			135.	a	Airflow testing		
			135.	b	HEPA filter integrity testing		
			135.	c	Total particle counts testing		
			135.	d	Smoke visualization studies		
			136.		When technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards or other equivalent means for certifying, does the PEC maintain the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			137.		Is temperature and humidity monitored in the SRPA or area containing a hot-cell?	**USP Chapter 825– 5.7 Environmental Controls - DAILY MONITORING OF ENVIRONMENT** The temperature and humidity must be monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure must monitored, each day that preparations are made, either manually or by a continuous recording device. These include: Relative humidity should be kept at 60% or lower; Temperature and relative humidity continuous readings must be confirmed daily to have remained within the acceptable range; Excursions must be documented and, if applicable, appropriate corrective actions taken; Temperature monitoring devices must be verified for accuracy every 12 months or as required by the manufacturer; Monitoring of pressure differentials must be performed. See Packaging and Storage Requirements <659> for information on controlled area temperature and allowable excursions.	
			138.		If in a classified area, is pressure monitored, each day that preparations are made, either manually or by a continuous recording device?		
			139.		Does environmental control include the following:		
			139.	a	Temperature and relative humidity continuous readings confirmed daily to have remained within the acceptable range		
			139.	b	Excursions documented and, if applicable, appropriate corrective actions taken		
			139.	c	Temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer		
			139.	d	Monitoring of pressure differentials are performed		
MICROBIOLOGICAL AIR AND SURFACE MONITORING							
			140.		Does the facility develop and implement written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	**USP Chapter 825– 6 MICROBIOLOGICAL AIR AND SURFACE MONITORING** An effective air and surface monitoring program provides information on the environmental quality of the classified areas where sterile radiopharmaceuticals	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			141.	Are air and surface monitoring results and corrective actions documented?	are processed. The program identifies environmental quality trends over time, potential routes of microbiological contamination, and allows for implementation of corrective actions to prevent microbiological contamination of the radiopharmaceuticals. Facilities must develop and implement written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas. Air and surface monitoring results and the corrective actions must be documented, and records must be readily retrievable as required by jurisdictional laws and regulations.	
			142.	Are records readily retrievable?		
			143.	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	**USP Chapter 825– 6.1 General Monitoring Requirements** The goals of an air and surface monitoring program are to determine whether microbiological contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained. The microbiological air and surface monitoring program must include viable impact volumetric airborne particulate sampling and surface sampling. Air and surface sampling must be performed initially for classified areas in a facility to establish a baseline level of environmental quality. After initial sampling, the classified areas must be monitored according to the minimum frequencies described in this section to ensure that the environment remains in a suitable state for aseptic processing tasks. The air and surface monitoring program involves the collection and evaluation of samples from various air and surface locations to detect viable microbiological contaminants. The data are then used to assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfection techniques and agents specified in the facility SOPs. Regular review	
			144.	Is air and surface sampling performed initially for classified areas in the facility?		
			145.	After initial sampling, are the classified areas monitored according to the minimum frequencies?		
			146.	Is regular review of the sampling data performed to detect trends?		
			147.	Are results reviewed in conjunction with personnel data?		
			148.	Is data reviewed following corrective actions?		
			149.	Is air and surface sampling conducted during actual or simulated dynamic operating conditions?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			150.	Is sampling performed in the following circumstances:		of the sampling data must be performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment. Evaluating results collected over a period of time can be useful in identifying trends or determining that a significant change has occurred, even when the results fall within the specified limits. In addition, results must be reviewed in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. Prompt corrective action in response to any adverse findings is required to maintain the necessary environmental quality for handling sterile radiopharmaceutical. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels (see Table 3 and Table 4). Air and surface sampling must be conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained. Due to radiation exposure concerns for the workers involved, it is permissible for sampling to be carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area. In this case, simulated tasks that are reflective of the routine aseptic activities are performed. In addition to the specific sampling frequencies described in this section, sampling must be performed in any of the following circumstances: In conjunction with the certification of new facilities and equipment; After any modification of facilities or equipment; In response to identified problems (e.g., positive growth in sterility tests of compounded	
			150.	a	In conjunction with the certification of new facilities and equipment		
			150.	b	After any modification of facilities or equipment		
			150.	c	In response to identified problems		
			150.	d	In response to identified trends		
			150.	e	In response to changes that could impact the controlled area environments		
			150.	f	Is air and surface sampling conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas?		
			150.	g	If conducted during actual sterile processing, is the monitoring program designed and conducted to minimize the chance that sampling would contribute to contamination of the sterile radiopharmaceuticals or the environment?		
			150.	h	Is the air and surface monitoring program described in the established SOPs of the facility?		
			151.	Does the air and surface monitoring program include the following:			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			151.	a	Diagram of the sampling locations	radiopharmaceuticals); In response to identified trends (e.g., repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination); In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved). To obtain an air and surface sample that is representative of the typical aseptic operating conditions at the facility, air and surface sampling must be conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas. If conducted during actual sterile processing, the monitoring program must be designed and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the sterile radiopharmaceutical(s) or the environment. The air and surface monitoring program must be clearly described in the established SOPs of the facility and must include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action. The locations of sampling should be carefully selected based on their relationship to the activities performed in the area. It is important to obtain samples from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and that are likely to be representative of the conditions throughout the area. Evaluating results collected over a period of time can be useful in identifying trends or determining that a significant change has occurred, even when the results fall within the specified limits. It is important that personnel who	
			151.	b	SOPs for collecting samples		
			151.	c	Frequency of sampling		
			151.	d	Size of samples		
			151.	e	Time of day of sampling in relation to activities in the classified areas		
			151.	f	Action levels that would trigger corrective action		
			152.		Are air sampling devices serviced and calibrated as recommended by the manufacturer?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						operate the equipment be trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling. All air sampling devices must be serviced and calibrated as recommended by the manufacturer.	
			153.	Is a monitoring program for viable airborne particles developed and implemented to assess microbiological air quality in all classified areas?		**USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles** A monitoring program for viable airborne particles must be developed and implemented to assess microbiological air quality in all classified areas.	
			154.	Is volumetric active air sampling of all classified areas using an impaction device conducted during dynamic operating or simulated operating conditions at least every 6 months?		**USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles - VIABLE AIR SAMPLING: TIMING AND LOCATIONS** Volumetric active air sampling of all classified areas (e.g., ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device must be conducted during dynamic operating or simulated operating conditions at least every 6 months. Air sampling sites must be selected in all classified areas. When conducting sampling of the PEC, care should be taken to avoid disturbing unidirectional airflow if taken during actual sterile processing activities. Viable air sampling must include: 1. Follow the manufacturer's instructions for operation of the air sampling device, including placement of media. 2. Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled. 3. At the end of the sampling, retrieve the media plates/devices and cover. 4. Invert the media and incubate at 30°–35° for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air). Include sample location and date. 5. Then incubate the inverted media at 20°–	
			155.	Are air sampling sites selected in all classified areas?			
			156.	Does viable air sampling include the following:			
			156.	a	Follow the manufacturer's instructions for operation of the air sampling device, including placement of media.		
			156.	b	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled.		
			156.	c	At the end of the sampling, retrieve the media plates/devices and cover.		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			156.	d	Invert the media and incubate at 30°–35° for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type. Include sample location and date.	25° for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air). Include sample location and date. Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location and incubated concurrently. Both samples could be TSA or one sample could be TSA and the other fungal media [e.g., malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. Incubate each sample in a separate incubator. Incubate one sample at 30°–35° for no less than 48 hours, and incubate the other sample at 20°–25° for no less than 5 days. Fungal media samples must be incubated at 20°–25° for no less than 5 days. Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample. Record the results of the sampling on an environmental sampling form based on sample type (i.e., viable air) and include the sample location, and sample date. A general microbiological growth medium that supports the growth of bacteria and fungi must be used (e.g., TSA medium). CoA(s) from the manufacturer must verify that the medium meets the expected growth promotion, pH, and sterilization requirements. Samples must be incubated in a temperature monitored incubator with a calibrated measuring device. The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented. Incubators used for microbiological testing must be placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out. All sampling activities must be performed by trained individuals.	
			156.	e	Then incubate the inverted media at 20°–25° for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type. Include sample location and date.		
			157.		Are fungal media samples incubated at 20°–25° for no less than 5 days?		
			158.		Is a general microbiological growth medium that supports the growth of bacteria and fungi used?		
			159.		Do CoAs from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?		
			160.		Are samples incubated in a temperature monitored incubator with a calibrated measuring device?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			161.	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device?		
			162.	Are incubator temperature results reviewed and documented?		
			163.	Are incubators used for microbiological testing placed in a location outside of any classified area or SRPA?		
			164.	Are incubators used for microbiological testing kept away from areas where compounding or sterile processing activities are carried out?		
			165.	Are sampling activities performed by trained individuals?		
			166.	If two pieces of media were collected at a single location, is all recovered growth on each documented?	**USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles - DATA EVALUATION AND ACTION LEVELS** Evaluate cfu counts against the action levels in Table 3 and in relation to previous data to identify adverse results and/or trends. If two pieces of media were collected at a single location, all recovered growth on each must be documented and action levels are applied individually to each plate/device (i.e., results from each cubic meter of air sampled must be compared to the action level for that area). If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Some examples of corrective action include process or facility improvements, personnel training,	
			167.	If two pieces of media were collected at a single location, are action levels applied individually to each plate/device?		
			168.	If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO classification levels of the area sampled, is the cause investigated?		
			169.	If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				classification levels of the area sampled, is corrective action taken?	cleaning and disinfecting, or HEPA filter replacement and/or repair, or reducing the BUD of the radiopharmaceutical during investigation and while carrying out the corrective action plan. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. If levels measured during viable air sampling exceed the levels in Table 3, an attempt must be made to identify any microorganism recovered to the genus level (see Microbial Characterization, Identification, and Strain Typing <1113>) with the assistance of a qualified individual (e.g., microbiologist or industrial hygienist).	
			170.	Is a corrective action plan dependent on the cfu count and the microorganism recovered?		
			171.	Is the corrective action plan documented?		
			172.	If levels measured during viable air sampling exceed the levels in Table 3, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
			173.	Are sampling sites and procedures described in the facility's SOP?	**USP Chapter 825– 6.3 Monitoring Surfaces for Viable Particles** Surface sampling is an important component of the maintenance of a suitably controlled environment for sterile radiopharmaceutical processing, especially because transfer of microbial contamination from improperly disinfected work surfaces (e.g., via inadvertent touch contact by personnel) is a potential source of contamination of the radiopharmaceutical(s). Surface sampling is useful for evaluating facility cleaning and material handling procedures, work surface cleaning and disinfecting procedures, and personnel competency in work practices such as proper cleaning and disinfection. All sampling sites and procedures must be described in the facility's SOP.	
			174.	Is surface sampling of classified areas and PECs conducted at least monthly?	**USP Chapter 825– 6.3 Monitoring Surfaces for Viable** - **SURFACE SAMPLING: TIMING AND LOCATIONS** Surface sampling of all classified areas and all PECs must be conducted at least monthly for the detection	
			175.	Is each classified area sampled?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			176.	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?	of microbial contamination. Each classified area must be sampled (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>). The DPA of the PEC, and any equipment permanently contained in the PEC, must be sampled. Staging or work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas are to be evaluated to determine the locations that pose the greatest risk of harboring microbial contamination. Surface sampling must be performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected. However, radiopharmaceutical personnel must also consider the appropriate exposure and contamination prevention measures prior to and while collecting samples. If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, measures must be taken to eliminate the risk (e.g., implementation of appropriate shielding, performing the sampling at a later time or alternate day).	
			177.	Is surface sampling performed at the end of radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?		
			178.	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?		
			179.	If the worker assesses that risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk?		
			180.	Are surface sampling devices containing microbial growth media used for sampling flat surfaces?	**USP Chapter 825– 6.3 Monitoring Surfaces for Viable - SURFACE SAMPLING: TIMING AND LOCATIONS** Surface sampling devices (e.g., plates, paddles, or slides) containing microbial growth media must be used for sampling flat surfaces. CoAs from the manufacturer must verify that the media meet the expected growth promotion, pH, and sterilization requirements. Surface sampling devices must contain general microbial growth media (e.g., TSA) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents. If used, contact plates must have a raised convex surface. Sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when	
			181.	Do CoAs from the manufacturer verify that the media meets expected growth promotion, pH, and sterilization requirements?		
			182.	Do surface sampling devices contain general microbial growth media supplemented with neutralizing additives?		
			183.	If used, do contact plates have a raised convex surface?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			184.	After sampling, is the sampled area cleaned and disinfected?	sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces. After sampling, the sampled area must be thoroughly cleaned and disinfected. Use the following procedures for surface sampling on flat surfaces: 1. Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device. 2. If using plates, invert the plates. 3. Incubate the surface sampling devices at 30°–35° for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (i.e., surface). Include sample location and date. 4. Incubate the device at 20°–25° for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (i.e., surface). Include sample location and date. Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location. 1. Both samples could be TSA or one sample could be TSA and the other fungal media (e.g., MEA or SDA). 2. Incubate each sample in a separate incubator. Incubate one sample at 30°–35° for no less than 48 hours, and incubate the other sample at 20°–25° for no less than 5 days. 3. If fungal media are used as one of the samples, incubate the fungal media sample at 20°–25° for no less than 5 days. 4. Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample. Record the results of the sampling. 5. Record the results of the sampling.	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			185.	If two devices were collected at a single location, is all recovered growth on each documented?	**USP Chapter 825– 6.3 Monitoring Surfaces for Viable - DATA EVALUATION AND ACTION LEVELS** Evaluate cfu counts against the action levels in Table 4 and examine counts in relation to previous data to identify adverse results or trends. If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each piece of media individually (i.e., results from each sampling device must be compared to the action level for the area). If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair, or reducing the BUD of the radiopharmaceutical(s) during investigation and while carrying out the corrective action plan. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. If levels measured during surface sampling exceed the levels in Table 4, an attempt must be made to identify any microorganism recovered to the genus level (see <1113>) with the assistance of a qualified individual (e.g., microbiologist or industrial hygienist).	
			186.	If two devices were collected at a single location, are action levels applied to each piece of media individually?		
			187.	If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, is the cause investigated?		
			188.	If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, is corrective action taken?		
			189.	Is data collected in response to corrective actions reviewed?		
			190.	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
			191.	Is the corrective action plan documented?		
				If levels measured during surface sampling exceed the levels in Table 4, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
CLEANING AND DISINFECTING						

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			192.	Are surfaces cleaned prior to being disinfected? ****Using an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner to accomplish both the cleaning and disinfection in one step is acceptable.****	**USP Chapter 825-7 CLEANING AND DISINFECTING** Cleaning and disinfecting are important because surfaces in classified areas and SRPAs are a potential source of microbial contamination of sterile radiopharmaceuticals. The process of cleaning involves removing organic and inorganic residues from surfaces, usually with a manual or mechanical process and a cleaning agent. The process of disinfecting involves destruction of microorganisms, usually with a chemical or physical agent. Surfaces must be cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, apply sterile 70% IPA to remove any residue. Cleaning and disinfecting surfaces should occur at the minimum frequencies specified in Table 5 or if activities are not performed daily, cleaning and disinfecting must be completed before initiating activities. The act of reducing or removing radioactivity (radioactive decontamination) from an object or surface must be balanced with the risk of spreading radioactive contamination. At times the best approach may be to shield the area until the radiation exposure levels are lower. This balance must be specified in SOPs (e.g., trigger levels for safe cleaning). The PEC should be checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading radioactive contamination in the PEC. All cleaning and disinfecting activities must be performed by trained and appropriately garbed personnel using facility-approved agents and procedures that must be described in written SOPs. Cleaning must be performed in the direction of most to least clean areas. The frequency, method(s), and location(s) of cleaning, disinfecting, and	
			193.	If sterile processing of radiopharmaceuticals are not performed daily, is cleaning and disinfecting completed before initiating these activities?		
			194.	Is reducing or removing radioactivity from an object or surface balanced with the risk of spreading radioactive contamination?		
			195.	Is the balance of reducing or removing radioactivity from an object or surface and risk of spreading radioactive contamination specified in SOPs?		
			196.	Are cleaning and disinfecting activities performed by trained and appropriately garbed personnel?		
			197.	Are cleaning and disinfecting activities performed using facility-approved agents?		
			198.	Are cleaning and disinfecting activities performed using procedures described in written SOPs?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			199.	Is cleaning performed in the direction of most to least clean areas?	sporicidal agent use must be established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and must be followed by all cleaning personnel. The manufacturer's direction or published data for the minimum contact time must be followed for the cleaning, disinfecting, and sporicidal agents used. When sterile 70% IPA is used, it must be allowed to dry. All cleaning, disinfecting, and application of sporicidal agents must be documented according to facility SOPs.	
			200.	Is the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent used established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable?		
			201.	Are written SOPs followed by cleaning personnel?		
			202.	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?		
			203.	When sterile 70% IPA is used, is it allowed to dry?		
			204.	Is cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?		
			205.	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	**USP Chapter 825-7.1 Cleaning, Disinfecting, and Sporicidal Agents** Cleaning and disinfecting agents must be selected and used with careful consideration of compatibilities, effectiveness, and user safety. Considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected (see	
			206.	Is the disinfectant allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer without being disturbed?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			207.	Is sterile 70% IPA used in the ISO Class 5 PEC?	*Disinfectants and Antiseptics* <1072>). After the disinfectant is applied on the surface to be disinfected, the disinfectant must be allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed. Only the 70% IPA used in the ISO Class 5 PEC must be sterile. Sporicidal agents must be used at least monthly on all surfaces in classified areas and SRPAs. Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties. See Table 6 for a summary of the purpose of the cleaning, disinfecting, and sporicidal agents.	
			208.	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?		
			209.	Are all cleaning supplies, with the exception of tool handles and holders, low-lint?	**USP Chapter 825-7.2 Cleaning Supplies** All cleaning supplies (e.g., wipers and mop heads), with the exception of tool handles and holders, must be low-lint and should be disposable. If disposable cleaning supplies are used, they must be discarded after each cleaning activity. Reusable cleaning tools must be made of cleanable materials (e.g., no wooden handles) and must be cleaned and disinfected before and after each use. Reusable cleaning tools must be dedicated for use in the classified areas or SRPAs and must not be removed from these areas except for disposal. They must be discarded after an appropriate amount of time, to be determined based on the condition of the tools. Cleaning supplies and solutions used in the classified areas and SRPAs should be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs. Dispose of cleaning supplies used in the classified areas and SRPAs in a manner that minimizes the potential for dispersing particulates into the air (e.g. with minimal agitation, away from work surfaces).	
			210.	Are disposable cleaning supplies discarded after each cleaning activity?		
			211.	Are reusable cleaning tools made of cleanable materials?		
			212.	Are reusable cleaning tools cleaned and disinfected before and after each use?		
			213.	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and not removed from these areas except for disposal?		
			214.	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			215.	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?	**USP Chapter 825– 7.3 Cleaning and Disinfecting the PEC** Clean and disinfect the PEC at the minimum frequencies specified in Table 5. If the PEC contains a removable work tray, all sides of the work tray and the area underneath the work tray must be cleaned and disinfected at least monthly. 1. Survey all surfaces of the PEC for radioactive contamination and follow facility SOPs to decontaminate, if necessary. 2. Remove, if necessary, any particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers. 3. Apply a cleaning agent followed by a disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved. 4. Apply sterile 70% IPA 5. Allow the surface to dry completely before beginning activities. 6. The PEC must be wiped with a sporicidal agent at least monthly.	
			216.	Is the PEC wiped with a sporicidal agent at least monthly?		
			217.	~~Are items wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers before they are introduced into a classified area or SRPA?~~ Are all shipping carton(s), corrugated or uncoated cardboard kept out of the classified areas and kept out of the perimeter of the SPRA?	**USP Chapter 825– 7.4 Disinfecting Supplies for Classified Areas and SRPAs** No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the classified area (e.g., clean side of ante-room) or within the perimeter of the SRPA. Before items are introduced into a classified area or SRPA, they must be wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers. After the sporicidal or sterile disinfectant is applied onto the surface, the agent must be allowed to dwell on the surface for the minimum contact time specified by the manufacturer (see 6.1 General Monitoring Requirements). The agent used for disinfecting the packaging must be compatible with the packaging and must not render the product label unreadable. Any	
			218.	Are items wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers before they are		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				introduced into a classified area or SRPA?	item to be transferred into the PEC from the classified area or SRPA must be disinfected with a sterile disinfectant (e.g., sterile 70% IPA). In the case of radiopharmaceuticals being processed by remote means in a hot-cell, the opening of sterile packages (e.g., syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area. In this case, the syringes may be opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle.	
			219.	Are sporicidal or sterile disinfectant agents allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer?		
			220.	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		
			221.	Is each item transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant?		
			222.	Are critical sites wiped with sterile 70% IPA?	**USP Chapter 825-7.5 Disinfecting Critical Sites** Critical sites (e.g., vial stoppers) must be wiped with sterile 70% IPA. The critical site must be wiped ensuring that both chemical and mechanical actions are used to remove contaminants. The sterile 70% IPA must be allowed to dry before piercing critical sites.	
			223.	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?		
			224.	Is sterile 70% IPA allowed to dry before piercing critical sites?		
			225.	Are radiation shielding and equipment that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area or SRPA?	**USP Chapter 825– 7.6 Cleaning and Disinfecting Items from Patient Care Area** Radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration must be cleaned and disinfected before returning to any	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			226.		Are syringes that have been used in a patient care area not brought back into the classified area or SRPA for re-assaying or disposal? ****A syringe may reenter a classified area or SRPA, if it is sealed inside an impervious container that is disinfected prior to entry.****	classified area (e.g., buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention guidelines1 as noncritical equipment requiring low-risk disinfection. Syringes that have been used in a patient care area must not be brought back into the classified area (e.g., buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (e.g., sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA. Equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs are considered mixed waste (e.g., syringe shields and syringe carrying containers). This equipment must be cleaned and disinfected through actions regulated by the facilities' SOPs. Equipment that contained or was in contact with mixed waste must be cleaned and disinfected with an appropriate agent(s) for blood.	
			227.		Is equipment cleaned and disinfected through actions regulated by the facilities' SOPs?		
					Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?		
ASSIGNING BUD							
			228.		If assigning a BUD longer than the manufacturer-stated/suggested use-by time interval, is there evidence to support the maintenance of appropriate quality and purity?	**USP Chapter 825– 8. Assigning BUD** BUDs are based on the risk of microbial contamination with the assumption that the radiopharmaceutical(s) should remain chemically and physically stable, and its container–closure system should maintain its integrity for the duration of the BUD (Table 7). The time starts at the moment of the first sterile vial puncture or exposure of a critical site (e.g., syringe tip, needle hub, or needle) to ambient air, whichever is first. The BUDs stated in Table 7 are maximum values in the absence of sterility testing, and the assigned BUD may be shorter for a variety of reasons discussed below. The individual responsible for the manipulation assigns the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature. For compounded preparations (sterile and nonsterile), the	
			229.		When assigning a BUD for a radiopharmaceutical(s), are the following considered:		
			228.	a	Sterility		
			228.	b	Radiochemical purity where the assigned BUD is based on stability studies		
			228.	c	Radionuclidic purity		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			228.	d	Age of generator eluate	BUD is also dependent on maintenance of appropriate quality and purity, including radiochemical purity, radionuclidic purity, and other applicable parameters as specified in individual monographs or as clinically appropriate. For preparations with minor deviations involving conventionally manufactured kits (sterile and nonsterile), the kit may state or suggest a use-by time in the package insert. For certain radiopharmaceuticals transportation time, radionuclide availability, and other factors may necessitate extending manufacturer-stated/suggested use-by time to meet patient needs. Assigning a BUD longer than the manufacturer-stated/suggested use-by time interval must be supported by evidence of the maintenance of appropriate quality and purity, including radiochemical purity and radionuclidic purity as specified in individual monographs, and other applicable parameters as clinically appropriate. Assignment of a BUD for a radiopharmaceutical(s) must consider several factors, as applicable. Issues of concern include, but are not limited to, the following: Sterility: Maintenance of sterility is a major concern for any sterile preparation or product. Good aseptic handling practices in an appropriate environmentally-controlled area are the most critical factors in ensuring sterility. See Table 7 for maximum BUD. The assigned BUD should not exceed the sterility-related times listed in Table 7, unless a longer time is justified by Sterility Tests <71>. Radiochemical purity: Maintenance of radiochemical purity is affected by a variety of factors including, but not limited to, storage temperature, quantity of radioactivity, radioactivity concentration, presence or absence of antioxidants or other stabilizing agents, and container type (e.g., glass vial vs. plastic syringe). The assigned BUD must be based on stability studies in which these variables are controlled and are representative of the conditions of actual use. For	
			228.	e	Number of particles including the increasing ratio over time of the number of particles per unit radioactivity.		
			228.	f	The specific activity of the patient dose contains no more than the specified maximum mass when radioactivity decays over time and the specific activity decreases resulting in more mass per unit radioactivity		
			228.	g	Container type that ensures proper storage		
			228.	h	Cell viability		
			228.	i	Expiration date assigned for manufactured radiopharmaceuticals that is distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing		
			228.	j	The assigned BUD of radiopharmaceuticals prepared from kits		
			228.	k	The shortest BUD of any component.		
			229.		Does the facility have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					factors that allow a range of values (e.g., storage temperature, quantity of radioactivity, radioactivity concentration), studies should be conducted at the extremes of the ranges. Radionuclidic purity: Because radionuclidic impurities may decay away more slowly than the primary radionuclide, the radionuclidic purity may decrease over time. For example, the ratio of Mo-99 (half-life of about 66 hours) to Tc-99m (half-life of about 6 hours) continuously increases over time. USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration. Calculation of radionuclidic purity at future times is necessary to ensure compliance throughout the assigned BUD. Age of generator eluate: As a generator eluate decays, the desired daughter radionuclide decays to form other nuclides and potential radiolytic products, which may interfere with radiolabeling of kits. For example, Tc-99m undergoes decay to Tc-99. More importantly, increasing amounts of peroxides formed as radiation interacts with water molecules. Increased amounts of Tc-99 and peroxides can interfere with the radiolabeling of many kits. Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits must take into account the build-up of Tc-99 and peroxides over time. Number of particles: For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. For example, the BUD for Tc-99m albumin aggregated [macroaggregated albumin (MAA)] must take into account the increasing ratio over time of the number of particles per unit radioactivity. For example, if an MAA kit is prepared such that the radioactive patient dose is 200,000 particles at the time of calibration, the same patient dose will contain 700,000 particles at 10.85 hours after calibration.	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					Calculation of the number of MAA particles in the patient dose is necessary to ensure compliance with the prescribed particle range throughout the assigned BUD. Specific activity: For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake (i.e., too much mass may result in saturation of receptor sites and reduce target uptake of the radiopharmaceutical). As radioactivity decays over time, specific activity decreases resulting in more mass per unit radioactivity. In such situations, the assigned BUD must ensure that the patient dose contains no more than the specified maximum mass. Container type: Because radiochemical stability or other quality attributes of a radiopharmaceutical may be affected by its container characteristics, the BUD for a radiopharmaceutical dose dispensed in a plastic syringe may be different than the BUD of that same radiopharmaceutical maintained in a glass vial. The assigned BUD must be determined in the proper storage container. Cell viability: The viability of radiolabeled blood cells (e.g., leukocytes) decreases over time, and may also be affected by other factors such as the suspending medium, temperature, and agitation. The assigned BUD should be as short as circumstances reasonably allow so as to maximize cell viability. In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s). In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation. A radiopharmaceutical may not exceed the shortest BUD of any of its components. The facility must have policies and SOPs appropriate to the assignment of BUD and	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					maintain documentation of applicable study results and calculations. Studies of radiolabeling efficiency and radiochemical stability should employ quality control (QC) testing methods described in the manufacturer's package insert, USP monographs and general chapters, or other equivalent testing methods and be sufficiently rigorous to allow statistical confidence in the results. The facility must have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs. Policies and SOPs should also be in place to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability.	
DOCUMENTATION						
			230.	Are applicable records, including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, dispensing radiopharmaceuticals?	**USP Chapter 825– 9. Documentation** Applicable records (hard-copy or electronic), including policies and SOPs, must be maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals. Such records include, but are not limited to: Personnel training and testing, including visual assessment of aseptic technique competency, validation, garbing, hand hygiene, equipment/environment cleaning and disinfecting, gloved fingertip and thumb sampling, and media fill evaluation initially and follow up testing at specified intervals; Testing and monitoring of environmental controls, including ISO classification, ACPH, pressure differentials, temperature, humidity and viable air/surface and total airborne particle test results; Equipment maintenance and cleaning/disinfecting; End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations;	

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
							Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding; Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature; Investigations and corrective actions and tracking of events to closure.	
			231.	Is the following data included in the MFR when a minor deviation or compounding occurs:			**USP Chapter 825– 9.1 Master Formulation Record** A MFR is required only for a preparation with minor deviations or compounding, as described in 11. Compounding. A MFR is not required for a preparation following the manufacturer's instructions. Data that must be included in the MFR are as follows: Name of the radiopharmaceutical; Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA); Detailed procedure (e.g., heating, components, incubation time); Range of radioactivity; Range of volume; Equipment to be used; PEC and SEC to be used, if applicable; Quality control tests to be performed for final release of the radiopharmaceutical (e.g., radiochemical purity, pH); Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits; Trained personnel; Garbing procedure, if different than	
			231.	a	Name of the radiopharmaceutical			
			231.	b	Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation			
			231.	c	Detailed procedure			
			231.	d	Range of radioactivity			
			231.	e	Range of volume			
			231.	f	Equipment to be used			
			231.	g	PEC and SEC to be used			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			231.	h	Quality control tests to be performed for final release of the radiopharmaceutical	standard procedure; Container(s); Reference source of the BUD assignment and storage conditions.	
			231.	i	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits		
			231.	j	Trained personnel		
			231.	k	Garbing procedure, if different than standard procedure		
			231.	l	Container(s)		
			231.	m	Reference source of the BUD assignment and storage conditions		
			232.		Does a record for preparation with minor deviation or compounding include the following:	**USP Chapter 825– 9.2 Records for Preparation with Minor Deviations/Compounding** A record for preparation with minor deviation or compounding must include the following: Name of the radiopharmaceutical; Physical form (e.g., capsule or solution); Name and quantity of ingredients including calibration time for radioactive ingredients (e.g., 100 mCi Tc 99m sodium pertechnetate @ 1300); Total volume; Reference to the MFR; Any deviation from the MFR, if applicable; Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components; Name of the person who prepared and name of the supervising personnel (e.g., ANP or AU physician); Date and time of preparation; Assigned internal identification number (e.g., lot number); Unique reference [e.g., prescription, order number(s)]; Assigned BUD and storage requirements; Documentation of QC results.	
			232.	a	Name of the radiopharmaceutical		
			232.	b	Physical form		
			232.	c	Name and quantity of ingredients including calibration time for radioactive ingredients		
			232.	d	Total volume		
			232.	e	Reference to the MFR		
			232.	f	Any deviation from the MFR, if applicable		
			232.	g	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			232.	h	Name of the person who prepared and name of the supervising personnel		
			232.	i	Date and time of preparation		
			232.	j	Assigned internal identification number		
			232.	k	Unique reference [e.g., prescription, order number(s)]		
			232.	l	Assigned BUD and storage requirements		
			232.	m	Documentation of QC results		
PREPARATION							
			233.		Does the individual responsible for preparing the radiopharmaceutical(s) ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD?	**USP Chapter 825– 10. Preparation** The individual responsible for preparing the radiopharmaceutical(s) must ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD. This includes, as appropriate for the reparation, radionuclidic purity, radiochemical purity, chemical purity, and physical and chemical properties.	
			234.		Do deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions?	**USP Chapter 825– 10.2 Preparation with Minor Deviations** In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA-approved labeling. Note that General Notices, 5.20.20.1 In Compounded Preparations includes the statement: "Deviation from the specified processes or methods of compounding, although not from the ingredients or proportions thereof, may occur provided that the finished preparation conforms to the relevant standards and to preparations produced by following	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					the specified process." However, except for a few receptor-based radiopharmaceuticals where specific activity is an important parameter, there is a very broad range of acceptable values for specific activity and for proportions of ingredients. Deviations from manufacturer preparation instructions for radiopharmaceuticals must maintain the same ingredients but may differ in their proportions. This requires appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or is supported by appropriate peer-reviewed publications for the minor deviation utilized. Examples of minor deviations include, but are not limited to, the following: Altering the quantity of radioactivity or volume added to the vial; Changes in step-by-step operations (e.g., dilute Tc-99m sodium pertechnetate after rather than before addition to the vial); Using alternative devices or equipment (e.g., a heating block rather than a hot water bath, using a different sized needle, different shielding materials); Using QC test methods other than those described in the product labeling (e.g., radiochemical purity); Filtering Tc-99m sulfur colloid.	
			235.	Are blood and blood components handled with required precautions using aseptic technique?	**USP Chapter 825– 10.3 Preparation of Radiolabeled Blood Components** Handling blood and radiolabeling of blood components requires special attention to biological risks and must be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered. Due to the potential presence of microorganisms in the original blood sample, the preparation must be administered as soon as possible but no later than 6 hours after the blood sample is	
			236.	Are blood sample preparations administered within 6 hours of receipt?		
			237.	Is there complete physical separation between where blood products are handled and non-blood products?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			238.	Are blood products labeled in ISO Class 5 BSC in an ISO Class 7 buffer area?	obtained from the patient or blood bank. The presence of microorganisms in a blood sample may present a risk to the individual performing the preparation as well as cross-contamination to other blood samples or other non-blood related radiopharmaceuticals. Equipment and supplies should never be shared with other activities unless they are first thoroughly cleaned and disinfected. Special precautions when radiolabeling of blood components for non-immediate use include: There must be complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs must be in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions; One radiolabeling procedure per PEC at a time. Blood products from more than one patient must never be manipulated at the same workstation at the same time. Each area should have dedicated supplies, equipment (including dose calibrator), and waste disposal to eliminate sharing of these items or overlap in pathways; Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, prior to starting another blood component radiolabeling procedure; If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator must be used or the dose calibrator dipper and liner must be cleaned and disinfected following the radioassay; Centrifuge should be located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes; Dedicated (per each radiolabeling procedure) consumable products (e.g., 0.9% sodium chloride injection, diluent,	
			239.	If more than one ISO class 5 PEC is located within the ISO Class 7 buffer area, are policies and SOP's in place?		
			240.	Are certifications in place that the SEC meets air quality at maximum occupancy under dynamic operating conditions?		
			241.	Is there only one radiolabeling procedure per PEC at a time?		
			242.	Are blood products from only one patient manipulated at each workstation at a time?		
			243.	If a dedicated dose calibrator is not available, is a dedicated dose calibrator available to prevent the blood containers from contaminating the calibrator?		
			244.	If a dedicated dose calibrator is not available, are dose calibrator dippers and liners cleaned and disinfected prior to the radioassay?		
			245.	Are all tubes and syringes in contact with patient blood components clearly labeled?		
			246.	Do SOP's address cleaning and disinfection process as required for blood-borne pathogens?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure; All tubes and syringes in contact with the patient's blood components must be clearly labeled with the patient's name and at least one additional identifier (e.g., date of birth, medical record number, barcode); Dedicated syringe shields and vial shields; Remove and replace any garb that enters the ISO Class 5 BSC before handling anything else not related to performing this procedure; Removal of all disposable items from the ISO Class 5 BSC utilized in each radiolabeling procedure; Cleaning and disinfection of all reusable equipment and components (e.g., BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) after each radiolabeling procedure prior to any further use. Policies and SOPs must address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient; After the completion of blood radiolabeling procedures, follow all requirements in 4.5 Hand Hygiene and Garbing for Buffer Areas and segregated Radiopharmaceutical Processing Area.	
			247.	Is in vitro red blood cell labeling prepared under the following conditions:		**USP Chapter 825-10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use** In vitro red blood cell labeling must be prepared while following the conditions below: A dedicated space for blood handling must be designated through the entirety of the blood radiolabeling process. This area must be free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection; Perform only one radiolabeling procedure at a time or have documented processes that maintain the integrity of samples and environment; Dedicated equipment must be used for blood radiolabeling procedure (e.g., L-block,	
			247.	a	A dedicated space for blood handling throughout the entirety of the blood radiolabeling process		
			247.	b	Area free from clutter and not used for any other preparations or handling prior to cleaning and disinfection		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			247.	c	Only one procedure labeled at a time or a documented process to maintain integrity of samples and environment	syringe shield, vial shield, forceps, needle recapper); If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product must be used to decontaminate the dipper and liner of the dose calibrator following the radioassay; A cleaning and disinfecting procedure with an appropriate agent(s) must be used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded; Follow all requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations; The start time of the preparation must begin with the initial container puncture or the exposure of a critical site (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first; BUD of 1 hour (see Table 7).	
			247.	d	Equipment dedicated for radiolabeling procedure		
			247.	e	Prevention of blood containers contaminating a dose calibrator if a dedicated dose calibrator is not available		
			247.	f	Dose calibrator cleaned and disinfected if a dedicated calibrator is not available		
			247.	g	Procedure for cleaning and disinfecting with appropriate products used to decontaminate the dipper and liner of the dose calibrator following the radioassay		
			247.	h	Cleaning and disinfecting procedure followed to decontaminate the area and equipment prior to and after the radiolabeling is complete		
			247.	i	Hand hygiene and garbing for immediate use followed		
			247.	j	The start time of the preparation begins with initial container puncture or exposure of critical site		
			247.	k	A BUD of 1 hour is used for expiration		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
COMPOUNDING						
			248.	Are there written procedures for compounding activity?	**USP Chapter 825-11 COMPOUNDING** Each compounding activity must be based on a pre-established written procedure and must include maintenance of compounding records. The compounding record must provide traceability (see 9. Documentation). All sterile compounding, using aseptic technique, must be performed in an ISO 5 PEC. Refer to 5.7 Environmental Controls and Table 7 for further clarification on the location of the PEC and the applicability of the radiopharmaceutical BUD. Compounding must not be performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness, unless part of an institutional review board approved investigational study. Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals must not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.	
			249.	Are there written procedures for maintenance of compounding records that provide traceability?		
			250.	Is sterile compounding performed in an ISO 5 PEC?		
			251.	Is compounding not performed with any radiopharmaceuticals that have been withdrawn from the market because of safety, lack of effectiveness, unless an institutional review board had approved for investigational study?		
			252.	Are radiopharmaceuticals not compounded that are essentially copies of FDA-approved radiopharmaceuticals unless there is a change that produces a clinical difference identified by the patient or prescriber?		
			253.	Are areas designated for nonsterile compounding clean, uncluttered, and separated from sterile radiopharmaceuticals?	**USP Chapter 825-11.1 Compounding Nonsterile Radiopharmaceuticals** Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical. Examples of compounding nonsterile radiopharmaceuticals include: changing the dosage form of a capsule to a solution, changing an intravenous dosage form to an oral dosage form, and radiolabeling a food for oral administration	
			254.	Does the placement of equipment and materials take into account a design that prevents cross-contamination?		
			255.	Does each compound have a unique MFR?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			256.		Are the ingredients obtained from the preferred sources?	(e.g., Tc-99m sulfur colloid in eggs). Areas designated for nonsterile compounding must be cleaned and uncluttered and separated from areas designated for sterile radiopharmaceuticals. Compounding should take into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable (e.g., chemical fume hood, activated charcoal filters when handling potentially volatile radionuclides). The placement of equipment and materials must take into account a design that prevents cross-contamination. When feasible, disposable material should be used to reduce the chance of cross-contamination. Each compound must have a unique MFR (see 9.1 Master Formulation Record). The preparation information is documented on a compounding record (see 9.2 Records for Preparation with Minor Deviations/Compounding). The MFR details the selection of all components. The ingredients must be obtained from sources in this preferential order: FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR must detail the selection of a material that is suitable for the intended use. The MFR must establish the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA). Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means. A BUD for the compounded radiopharmaceutical must be validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions. A BUD cannot be extended past the labeled expiration date of any component in the compound. If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor	
			257.		Does the MFR detail ingredients obtained from other sources that are suitable for the intended use?		
			258.		Does the MFR establish the following for non-preferred sources by validated means:		
			258.	a	Identity		
			258.	b	Strength		
			258.	c	Purity		
			258.	d	Quality		
			259.		Are BUD's for the compounded radiopharmaceuticals validated?		
			260.		Does the BUD not extend past the shortest BUD of any components?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					deviations, the BUD of the final compounded radiopharmaceutical must not exceed the shortest remaining BUD of any of those components.	
			261.	Do personnel responsible for compounding consider all possible interactions between components?	**USP Chapter 825-11.2 Sterile Compounding** Personnel responsible for compounding must consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD. In some cases, this may require systematic QC testing over time to validate the appropriateness of a particular BUD. Another activity that is considered a compounding activity is the splitting of conventionally marketed kits. Kit-splitting (also referred to as "fractionation") may be used to meet patient need. For example, the contents of a kit vial can be reconstituted with 0.9% sodium chloride injection and aliquoted into other containers for storage and subsequent radiolabeling. The individual responsible must consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD. Systematic QC testing is required to validate the appropriateness of a particular BUD.	
			262.	Does the individual responsible consider all the possible interactions and alteration of stability for kit components if kit-splitting is used?		
			263.	If nonsterile components are used is a sterilization and testing procedure performed?	**USP Chapter 825-11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components** Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides. If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (e.g., filtration with bubble point testing) and testing described in (85) must be performed. The designated	
			264.	Does the designated person for compounding consider all possible interactions between components, such as stability, radiochemical stability, solubility, and other parameter?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			265.	Does compounding of bulk drug substances comply with USP and NF monograph standards?	person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity, and must consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD. This may require testing to validate the appropriateness of a particular BUD. If compounding involves a bulk drug substance, the radiopharmaceutical must comply with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product. For this chapter, a bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical. Each bulk drug substance should be manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures. If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients must comply with standards of an applicable USP or NF monograph, if one exists. It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	
			266.	Does compounding with excipients or other inactive ingredients comply with USP and NF monograph standards?		
DISPENSING						
			267.	Are all opened or final dose form not from the manufacturer radioassayed?	**USP Chapter 825-12.1 Dispensing and Radioassay** Except for an unopened manufacturer container, the final dose or ordered amount must be radioassayed (i.e., in a dose calibrator). The measured activity should be mathematically corrected for radioactive decay to the time of scheduled administration (calibration time) (refer to 14. Quality Assurance and Quality Control).	
			268.	Is the activity at calibration within limits?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						The activity at calibration time must always be within federal, state, and local variance limits.	
			269.	Does the inner container labeling of radiopharmaceuticals meet the following minimum requirements?		**USP Chapter 825-12.2 Labeling** The labeling of radiopharmaceuticals can fall under the jurisdiction of numerous regulatory agencies. Individual boards of pharmacy and other regulatory bodies may have very specific statutes and/or regulations concerning this process. The requirements specified in this chapter must be considered the minimum requirements for the labeling of the inner container (e.g., syringe, vial) and the outer shielding (e.g., syringe or vial shielding). Therefore, all personnel distributing and/or dispensing radiopharmaceuticals should verify that any labeling is in compliance with regulatory agencies. The inner container must be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; For all therapeutic and blood-products, the patient name/identifier; Radionuclide and chemical form (generic name); Radioactivity at the date and time of calibration. The outer shielding must be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; For all therapeutic and blood-products, the patient name/identifier; Radionuclide and chemical form (generic name); Radioactivity at the date and time of calibration; Volume or number of units dispensed (e.g., 2 capsules), as applicable; Product expiration or BUD (see Table 7), as applicable, and any special storage and handling instructions for nonimmediate use (e.g., refrigeration, resuspension); Route of administration.	
			269.	a	Standard radiation symbol		
			269.	b	The words "Caution—Radioactive Material"		
			269.	c	For all therapeutic and blood-products, the patient name/identifier		
			269.	d	Radionuclide and chemical form (generic name)		
			269.	e	Radioactivity at the date and time of calibration		
			270.	Does the outer shielding labeling of radiopharmaceuticals meet the following minimum requirements:			
			270.	a	Standard radiation symbol		
			270.	b	The words "Caution—Radioactive Material"		
			270.	c	For all therapeutic and blood-products, the patient name/identifier		
			270.	d	Radionuclide and chemical form (generic name)		
			270.	e	Radioactivity at the date and time of calibration		
			270.	f	Volume or number of units dispensed, as applicable		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			270.	g	Product expiration or BUD (see Table 7), as applicable, and any special storage and handling instructions for nonimmediate use		
			270.	h	Route of administration		
			271.		Do all operators of the direct infusion systems follow the "Instructions for Use" in the device labeling?	**USP Chapter 825-12.3 Direct Infusion Systems** The information in this section is limited to the sterility and aseptic technique for direct infusion systems. The described infusion systems are FDA-cleared medical devices or FDA-approved direct infusion generators without an ISO-5 environment. The manner in which all necessary solutions (e.g., radiopharmaceutical and eluant/diluent) are used in conjunction with the system was a consideration in the overall approval process for the system. Therefore, all operators of the direct infusion systems must follow the "Instructions for Use" in the device labeling. Direct infusion generators (e.g., rubidium chloride Rb 82 injection) may employ a container of eluant (e.g., bag of 0.9% sodium chloride injection) to allow administration of the eluate directly to patient(s); Direct infusion devices (e.g., portable PET patient-infusion system) provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical (e.g., fludeoxyglucose F 18 injection) and the diluent (e.g., 0.9% sodium chloride injection) directly to patients to reduce the radiation exposure to personnel. In each of these situations, the radiopharmaceutical container must be attached to or be needle-punctured by the respective direct infusion system. Given that such direct infusion systems are intended for multiple patients over the course of several hours, there could be a sterility concern if not operated properly. Therefore, the following parameters must be considered by the operator of the system: Setup attachment or needle-	
			272.		In the following situations, is the radiopharmaceutical container attached to or needle-punctured by the respective direct infusion system:		
			272.	a	Direct infusion generators that employ a container of eluant to allow administration of the eluate directly to patient(s)		
			272.	b	Direct infusion devices that provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical directly to patients to reduce the radiation exposure to personnel		
			273.		Are the following parameters considered by the operator of the system if it is intended for multiple patients over the course of several hours:		
			273.	a	Setup attachment or needle-puncture should be performed in a defined environment		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			273.	b	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table 7)	puncture should be performed in a defined environment; Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table7). The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag must be labeled with the date and time of puncture and the BUD; Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial must be disinfected with sterile 70% IPA prior to puncturing the vial with the needle; The septum of any vial and the ports of any diluent bag must be wiped with sterile 70% IPA prior to puncturing; When puncturing the vial in ambient air, it must only be punctured once; If there are problems with the infusion device, no sterile container(s) associated with the system can be repunctured or transferred to a PEC for further manipulations and the container, with contents, must be discarded.	
			273.	c	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag must be labeled with the date and time of puncture and the BUD		
			273.	d	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial must be disinfected with sterile 70% IPA prior to puncturing the vial with the needle		
			273.	e	The septum of any vial and the ports of any diluent bag must be wiped with sterile 70% IPA prior to puncturing		
			273.	f	When puncturing the vial in ambient air, it must only be punctured once		
			273.	g	If there are problems with the infusion device, no sterile container(s) associated with the system can be repunctured or transferred to a PEC for further manipulations and the container, with contents, must be discarded		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			274.		Are the following standards followed if transporting generators between facilities:	**USP Chapter 825- 12.4 Transporting Generators Between Facilities** The following standards must be followed if transporting generators between facilities: The generator needle and/or ports must be capped in ISO Class 8 air or better with sterile protectors; The generator must be packaged and transported in a manner to maintain the integrity and sterility of the generator system.	
			274.	a	The generator needle and/or ports capped in ISO Class 8 air or better with sterile protectors		
			274.	b	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system		
REPACKAGING							
			275.		Are opened or repackaged radiopharmaceuticals radioassayed?	**USP Chapter 825-13 REPACKAGING** Repackaging refers to the act of removing conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients. Repackaging may be performed for nonsterile radiopharmaceuticals (e.g., I-131 sodium iodide oral capsules) and for sterile radiopharmaceuticals (e.g., thallous chloride Tl 201 injection). Except for unopened manufacturer dosage units (e.g., capsules, Xe-133 vials), the repackaged radiopharmaceutical must be radioassayed (i.e., in a dose calibrator). The inner container should be labeled with the following: Standard radiation symbol; The words “Caution—Radioactive Material”; The radionuclide and chemical form (generic name); Radioactivity with units at time of calibration and the calibration time The outer shielding should be labeled with the following: Standard radiation symbol; The words “Caution—Radioactive	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						Material"; The radionuclide and chemical form (generic name); Radioactivity with units at time of calibration and the calibration time; Volume, or number of units (e.g., capsules), as applicable; Product expiration or BUD (see Table 7), as applicable; Special storage and handling instructions.	
QUALITY ASSURANCE AND QUALITY CONTROL							
			276.	Do the facility's QA and QC programs establish and document in SOPs that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable laws and regulations?		**USP Chapter 825-14 QUALITY ASSURANCE AND QUALITY CONTROL** Quality assurance (QA) is a system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards (see Quality Assurance in Pharmaceutical Compounding 1163). Quality control (QC) is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical(s). A facility's QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations. A designated person must ensure that the facility has formal, written QA and QC programs that establish a system of: 1. Adherence to procedures, 2. Prevention and detection of errors and other quality problems, 3. Evaluation of complaints and adverse events, and 4. Appropriate investigations and corrective actions. The SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program. The overall QA and QC program must be reviewed at least once every 12 months by the designated person. The results of the review must be	
			277.	Does a designated person ensure that the facility has written QA and QC programs that establish a system of the following:			
			277.	a	Adherence to procedures		
			277.	b	Prevention and detection of errors and other quality problems		
			277.	c	Evaluation of complaints and adverse events		
			277.	d	Appropriate investigations and corrective actions		
			278.	Do the SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program?			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			279.		Is the overall QA and QC program reviewed at least once every 12 months by the designated person?	documented and appropriate corrective action taken, if needed.	
			280.		Are the results of the review documented and appropriate corrective action taken, if needed?		
			281.		Does the facility have SOPs if a radiopharmaceutical is dispensed or administered before the results of release testing are known?	**USP Chapter 825-14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals** If a radiopharmaceutical is dispensed or administered before the results of release testing are known, the facility must have SOPs in place to: 1. Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes), and 2. Determine whether a recall is necessary. The SOP for recall of out-of-specification dispensed radiopharmaceuticals must contain procedures to: Determine the severity of the problem and the urgency for the implementation and completion of the recall; Determine the distribution of any affected radiopharmaceutical, including the date and quantity; Identify patients who have received the radiopharmaceutical; Outline the disposition and reconciliation of the recalled radiopharmaceutical The facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (e.g., state board of pharmacy, state health department).	
			282.		Does the facility's SOPs include the following:		
			282.	a	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm		
			282.	b	Determine whether a recall is necessary		
			283.		Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain procedures to:		
			283.	a	Determine the severity of the problem and the urgency for the implementation and completion of the recall		
			283.	b	Determine the distribution of any affected radiopharmaceutical, including the date and quantity		
			283.	c	Identify patients who have received the radiopharmaceutical		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			283.	d	Outline the disposition and reconciliation of the recalled radiopharmaceutical		
			284.		Does the facility document the implementation of recall procedures?		
			285.		Are recalls reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction?		
			286.		Has the radiopharmaceutical facility developed and implemented SOPs for handling complaints?	**USP Chapter 825-14.2 Complaint Handling** Radiopharmaceutical facilities must develop and implement SOPs for handling complaints. Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical. A designated person must review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical. If a complaint does, an investigation into the potential cause of the problem must be completed. The investigation must consider whether the quality problem could extend to other radiopharmaceuticals. Corrective action, if necessary, must be implemented for all potentially affected radiopharmaceuticals. Consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected. A readily retrievable record (written or electronic) of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., e-mail, telephone, mail). The record must contain the name of the complainant, the date the complaint was received, the nature of the complaint, the response to	
			287.		Does a designated person review all complaints?		
			288.		Is an investigation into the potential cause of the problem completed if a complaint indicates potential quality problems with the radiopharmaceutical?		
			289.		Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?		
			290.		Is a corrective action implemented, if necessary, for all potentially affected radiopharmaceuticals?		
			291.		Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			292.	Does the record contain the following:		the complaint, and, if known, the name and strength of the radiopharmaceutical and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record keeping requirements in 9. Documentation. A radiopharmaceutical that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations.	
			292.	a	The name of the complainant		
			292.	b	The date the complaint was received		
			292.	c	The nature of the complaint		
			292.	d	The response to the complaint		
			292.	e	The name and strength of the radiopharmaceutical (if known)		
			292.	f	The assigned internal identification number		
			292.	g	The findings of any investigation		
			292.	h	Any follow-up of any investigation		
			293.	Are records of complaints retrievable for review and evaluation for a possible trend?			
			294.	Are records of complaints retained in accordance with the record keeping requirements in 9. Documentation?			
			295.	Are returned radiopharmaceutical in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable laws and regulations?			
			296.	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in		**USP Chapter 825-14.3 Adverse Event Reporting** Adverse events potentially associated with the quality of radiopharmaceuticals must be reported in	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				accordance with the facility's SOPs and all applicable laws and regulations?	accordance with the facility's SOPs and all applicable jurisdictional laws and regulations. In addition, adverse events potentially associated with the quality of the radiopharmaceutical preparation should be reported to the applicable jurisdictional regulatory body (e.g., state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).	

Table 7. Preparation Conditions for Sterile Radiopharmaceuticals[1]

Preparation Conditions			
Manipulation	**PEC**	**SEC**	**BUD (hours)**
Immediate use	--	--	1
Direct infusion system, one puncture only (e.g., PET patient infusion system, Rb-82 generator)	--	--	10
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	SRPA	12

[1] The United States pharmacopeia. National formulary. General Chapter <825>. Rockville (MD): United States Pharmacopeial Convention; 2020. Table 7; p.17.

Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	SRPA with ISO Class 8 total airborne particle count	12
Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using sterile components	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	96
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using a nonsterile component and performing sterilization procedure (e.g., filtration with bubble point testing) but without performing *Sterility Tests* (71) testing	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	24
Radiolabeled blood components for immediate use [e.g., Tc 99m red blood cells (RBC)]	--	--	1
Radiolabeled blood components (e.g., radiolabeled leukocytes)	ISO Class 5 BSC	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	6 h after the blood sample is obtained

EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 01, 2022
TIME: 4:42 PM

WSR 22-22-092

Agency: Department of Health – Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) WAC 246-945-162, Pharmacist license qualifications, WAC 246-945-200, Pharmacy assistants, and WAC 246-945-205, Pharmacy technician certification. The Pharmacy Quality Assurance Commission (commission) is proposing permanent amendments to remove specific requirements for AIDS education requirements. These amendments are in response to the repeal of statutory authority for specific AIDS education trainings by Engrossed Substitute House Bill (ESHB) 1551 (Chapter 76, Laws of 2020). Other formatting changes are also proposed.

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of the proposed amendments to WAC 246-945-162, WAC 246-945-200, and WAC 246-945-205 is to align the rules with statutory amendments under ESHB 1551, which repealed the statutory requirement for health care professionals to complete AIDS education and training. Removing this requirement from WAC 246-945-162, WAC 246-945-200, and WAC 246-945-205 will align the rules with the statute and complete the commissions implementation of ESHB 1551.

Other amendments are necessary in the above cited sections to align rule language with current formatting standards and statutory citations.

Reasons supporting proposal:
The commission is proposing the repeal of specific AIDS education and training requirements as it is no longer supported by statute and it is intended to reduce stigma towards people living with HIV/AIDS.

Statutory authority for adoption: RCW 18.64.005; RCW 1864A.020; and RCW 18.64A.030

Statute being implemented: ESHB 1551 (chapter 76, Laws of 2020)

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111Israel Rd Tumwater, WA 98501	360-236-2987
Enforcement:	Joshua Munroe	111 Israel Rd Tumwater, WA 98501	360-236-2987

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☐ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☒ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The statutory authority for the rule has been repealed. The proposed rule language will align with amendments made by ESHB 1551 (chapter 76, Laws of 2020). The proposed rule also reflects amendments required by the Code Reviser to align rule language with current formatting standards.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

Name: Joshua Munroe
Agency: Pharmacy Quality Assurance Commission
Address: PO Box 47852 Olympia, WA 98504-7852
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AND RECEIVED BY (date) 1/3/2023

Date: November 1, 2022

Name: Teri Ferreira, RPh

Title: Pharmacy Quality Assurance Commission Chair

Signature:

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-162 Pharmacist license qualifications. (1) In addition to the requirements in RCW 18.64.080, an applicant for a pharmacist license who holds a baccalaureate degree in pharmacy or a doctor of pharmacy degree from a commission accredited school or college of pharmacy shall submit documentation of education and practice experience as follows:

(a) An applicant who graduated before July 1, 2020, whose official transcripts confer or award a baccalaureate of pharmacy or doctorate of pharmacy degree shall provide certification of at least ((~~fifteen hundred~~)) 1500 pharmacy internship hours in accordance with WAC 246-945-163.

(b) An applicant who graduates after July 1, 2020, whose official transcripts confer or award a doctorate of pharmacy is deemed to have satisfied the pharmacy practice experience and education requirements for licensure without documentation of internship hours.

(2) An applicant for a pharmacist license whose academic training in pharmacy is from institutions in foreign countries shall:

(a) Achieve certification by FPGEC including:

(i) Passing FPGEE;

(ii) Passing required TOEFL iBT;

(b) Provide official transcripts or diploma that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred; and

(c) Certification of a minimum of ((~~fifteen hundred~~)) 1500 pharmacy internship hours in accordance with WAC 246-945-163.

(3) An applicant for a pharmacist license shall take and pass pharmacist licensure examinations as defined in WAC 246-945-165.

((~~(4) An applicant for a pharmacist license shall provide proof of completion of seven hours of AIDS education as required in chapter 246-12 WAC, Part 8. The applicant is exempt from this requirement if they are a graduate of a commission accredited school or college of pharmacy because the curriculum satisfies this requirement.~~))

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-200 Pharmacy assistants. (1) To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-020.

(2) ((~~An initial applicant shall complete four hours of AIDS education as required in chapter 246-12 WAC, Part 8.~~

~~(3)~~)) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.

((~~(4)~~)) (3) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-205 Pharmacy technician certification. (1) An applicant for a pharmacy technician certification shall be ((~~eighteen~~)) 18 years of age and hold a high school diploma or GED.

(2) To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020, and:

(a) Provide proof of completion of eight hours of guided study of Washington state and federal pharmacy law. The law study shall be done in coordination and oversight of a Washington licensed pharmacist.

(b) ((~~Provide proof of four hours of AIDS education as required in chapter 246-12 WAC, Part 8, the applicant is exempt if they have completed a commission-approved training program whose program materials on file with the commission office document four hours of AIDS education.~~

~~(c)~~)) Provide proof of successful completion of a commission-approved pharmacy-technician training program WAC 246-945-215. Acceptable documentation includes:

(i) On-the-job training program. Successful completion of didactic and practice experience signed by the program director on a form provided by the commission; or

(ii) Formal academic or college programs. Official transcripts of completion of a diploma or certificate program at a pharmacy technician school or a two-year associate degree program, which shall include evidence of practice training hours; or

(iii) Certificate of Release or Discharge from Active Duty, DD214 documenting evidence of pharmacy technician training provided by a branch of the federal armed services.

((~~(d)~~)) (c) Pass a national certification examination approved by the commission within one year of completing a commission-approved training program and applying for certification, unless otherwise authorized by the commission.

(3) An applicant who is a graduate of a foreign school, university or college of pharmacy or medicine, whose professional degree program is approved by the commission shall complete the following:

(a) If English is not the primary language, the applicant shall take and pass TOEFL iBT;

(b) Complete ((~~five hundred twenty~~)) 525 hours of supervised experience under the supervision of a licensed pharmacist with training hours reported using forms provided by the commission; and

(c) Pass a national certification examination approved by the commission.

(4) An out-of-state pharmacy technician applicant must meet the same requirements as a pharmacy technician trained in Washington state.

Additional Changes to Consider for Technical Fixes Rules Package

Topic	WAC Number	Description	Previously Authorized by Commission
Typo	246-945-001 (44)(a)	Replace "technician(s)" with "pharmacy ancilliary personnel and interns"	Yes
Typo	246-945-011 (3)(b)	Should be "OTC" not "OTC's"	Yes
Typo	246-945-001(30)	Add means after electronic means	Yes
Question	246-945-063	"Registered product" needs to be changed to "restricted product"	Yes
Reorder subsections	246-945-417	Subsection (7) should be subsection (1). Or sub (7) should read that (1) through (6) apply.	Yes
Update	246-945-590	Subsection (6) amended to replace "as required to the FDA, commission and/or appropriate federal or state agency" with "to the FDA, commission, and, as applicable, the DEA"	Yes
Update	246-945-230	Change "original" licensee to "initial" license. We changed original to initial in the fee rule per the department's request. They want it uniform across professions. Need to make corresponding change in rule.	Needs approval
Fee rule references	chapter 246-945 WAC	All fee rule references will need to be updated to refer to new fee rules chapter	Needs approval
Missing conjunction	246-945-018	Missing an "and" or an "or" before "medications dispensed by a LTC…"	Needs approval
Update reference	246-945-590	Update reference WAC 246-960-330 to WAC 246-945-585	Needs approval

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 20, 2022
TIME: 2:18 PM

WSR 22-22-006

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-010 Prescription and chart order - Minimum requirements. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease 2019 (COVID-19) outbreak. Because a federal public health emergency is set to be in effect until at least January 2023, this extension will continue to reduce the burden on practitioners through the end of the federal public health emergency. This adopted emergency rule will extend WSR 22-13-180 filed on June 22, 2022. This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was refiled on July 10, 2020 after the commission's new chapter went into effect under WSR 20-15-058. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-010
Suspended: None

Statutory authority for adoption: RCW 18.64.005; chapter 69.50 RCW

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. This rule would allow patients and providers, especially pain patients, to limit their COVID-19 exposure both in the broader community and in the various health care settings. Interested parties and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the US Drug Enforcement Agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout the federal public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	1	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: 10/20/2022

Name: Teri Ferreira, RPh

Title: Pharmacy Quality Assurance Chair

Signature:

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 10, 2022
TIME: 11:56 AM

WSR 22-23-073

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, and 246-945-728 - Medication assistance. As provided in RCW 69.41.010 (15) the Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW. This adopted emergency rule will extend WSR 22-15-049 filed on July 15, 2022. This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department...

These emergency rules provide further definitions for terms used within this definition such as "enabler" and establish those "other means of medication assistance as defined by rule adopted by the department." These rules help impacted individuals retain their independence and live in the least restrictive setting, such as their own home, longer by providing means and guidance for medication assistance.

Citation of rules affected by this order:

New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246- 945-724, 246-945-726, 246-945-728

Repealed: None

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.41.010(15); RCW 69.41.075

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the

department work on permanent rulemaking. The CR101 was filed on December 27, 2021 under WSR 22-02-015. Permanent rulemaking was delayed due to the coronavirus disease 2019 pandemic. The commission and the department continue to work on draft language and plan to begin workshops in the spring of 2023.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

New	10	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	10	Amended	0	Repealed	0

Date Adopted: November 10, 2022 **Name:** Teri Ferreira, RPh and Kristin Peterson, JD **Title:** Pharmacy Quality Assurance Chair and Chief of Policy for Secretary of Health	**Signature:** 

PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. (1) This section through WAC 246-945-728 only apply to medication assistance provided in community-based care settings and in-home care settings.

(2) The following definitions apply to this section through WAC 246-945-728 unless the context requires otherwise:

(a) "Medication" means legend drugs and controlled substances; and

(b) "Practitioner" has the same meaning as in RCW 69.41.010(17).

NEW SECTION

WAC 246-945-712 Self-administration with assistance, independent self-administration, and medication administration. (1) Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into their mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that they are receiving medication. Assistance may be provided by a nonpractitioner with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous or injectable medication is specifically excluded. The individual/resident retains the right to refuse medication. Self-administration with assistance shall occur immediately prior to the ingestion or application of a medication.

(2) Independent self-administration occurs when an individual/resident is independently able to directly apply a legend drug or controlled substance by ingestion, inhalation, injection or other means. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. These regulations do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

(3) If an individual/resident is not able to physically ingest or apply a medication independently or with assistance, then the medication must be administered to the individual/resident by a person legally authorized to do so (e.g., physician, nurse, pharmacist). All

laws and regulations applicable to medication administration apply. If an individual/resident cannot safely self-administer medication or self-administer with assistance or cannot indicate an awareness that they are taking a medication, then the medication must be administered to the individual/resident by a person legally authorized to do so.

NEW SECTION

WAC 246-945-714 Self-administration with assistance in a community-based care setting or an in-home setting. (1) An individual/resident, or their representative, in a community-based care setting or an in-home setting may request self-administration with assistance.

(2) No additional separate assessment or documentation of the needs of the individual/resident are required in order to initiate self-administration with assistance. It is recommended that providers document their decision-making process in the health record of the individual or resident health record.

(3) A nonpractitioner may help in the preparation of legend drugs and controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

NEW SECTION

WAC 246-945-716 Enabler. (1) Enablers are physical devices used to facilitate an individual's/resident's self-administration of a medication. Physical devices include, but are not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled syringes, syringes used to measure liquids, specially adapted table surface, straw, piece of cloth, or fabric.

(2) An individual's hand may also be an enabler. The practice of "hand-over-hand" administration is not allowed. Medication administration with assistance includes steadying or guiding an individual's hand while he or she applies or instills medications such as ointments, eye, ear, and nasal preparations.

NEW SECTION

WAC 246-945-718 Alteration of medication for self-administration with assistance. Alteration of a medication for self-administration with assistance includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals/residents must be aware that the medication is being altered or added to their food.

NEW SECTION

WAC 246-945-720 Medication alteration. A practitioner practicing within their scope of practice must determine that it is safe to alter a legend drug or controlled substance. If the medication is altered, and a practitioner has determined that such medication alteration is necessary and appropriate, the determination shall be communicated orally or by written direction. Documentation of the appropriateness of the alteration must be on the prescription container, or in the individual's/resident's record.

NEW SECTION

WAC 246-945-722 Types of assistance provided by nonpractitioner. A nonpractitioner can transfer a medication from one container to another for the purpose of an individual dose. Examples include: Pouring a liquid medication from the medication container to a calibrated spoon or medication cup.

NEW SECTION

WAC 246-945-724 Oxygen order/prescription requirements. Under state law, oxygen is not a medication and is not covered under this rule. While oxygen is not considered a medication under state law, oxygen does require an order/prescription from a practitioner.

NEW SECTION

WAC 246-945-726 Self-administration with assistance of medication through a gastrostomy or "g-tube." If a prescription is written as an oral medication via "g-tube," and if a practitioner has determined that the medication can be altered, if necessary, for use via "g-tube," the rules as outlined for self-administration with assistance would also apply.

NEW SECTION

WAC 246-945-728 Other medication assistance requirements. A practitioner, nonpractitioner, and an individual/resident or their representative should be familiar with the rules specifically regulating the residential setting. The department of social and health services has adopted rules relating to medication services in assisted living facilities and adult family homes.

Uniform Facilities Enforcement Framework
Pharmacy Draft
Z-0262.1/23

Sec. 29. RCW 18.64.005 and 2022 c 240 s 15 are each amended to read as follows:

The commission shall:

(1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;

(2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists or pharmacy interns;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the commission, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW or a presiding officer designated by the commission. The commission may authorize the secretary, or their designee, to serve as the presiding officer for any disciplinary proceedings of the commission ((~~authorized under this chapter~~)). The presiding officer shall not vote on or make any final decision in cases pertaining to standards of practice or where clinical expertise

is necessary. All functions performed by the presiding officer shall be subject to chapter 34.05 RCW;

(5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the commission;

(6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for ((~~refusal~~)) denial of an application, assessment of a civil fine, imposition of a limited stop service, imposition of reasonable conditions, suspension, ((~~or~~)) revocation, or modification of licenses or any other authority to practice issued by the commission;

(8) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of the commission. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;

(10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;

(11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;

(12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;

(13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and

promote coordination of agencies responsible for ensuring compliance with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers;

(14) Whenever the workload of the commission requires, request that the secretary appoint pro tempore members. While serving as members pro tempore persons have all the powers, duties, and immunities, and are entitled to the emoluments, including travel expenses, of the commission.

Sec. 30. RCW 18.64.011 and 2021 c 78 s 1 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.

(3) "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.

(4) "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.

(5) "Commission" means the pharmacy quality assurance commission.

(6) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and

mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(9) "Department" means the department of health.

(10) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(11) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(13) "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(14) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(15) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

(16) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

(17) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.

(18) "Labeling" means the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(19) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(20) "Long-term care facility" means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW.

(21) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(22) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(23) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(24) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(25) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

(26) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

(27) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(28) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(29) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(30) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(31) "Secretary" means the secretary of health or the secretary's designee.

(32) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill

authorizations, reviewing therapeutic interventions, or reviewing chart orders.

(33) "Wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(34) "Directed plan of correction" means a plan devised by the commission that includes specific actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(35) "Immediate jeopardy" means a situation in which a licensee's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of individuals or animals at risk for serious injury, serious harm, serious impairment, or death.

(36) "License," "licensing," and "licensure" shall be deemed equivalent to the terms "approval," "credential," "certificate," "certification," "permit," and "registration" and an "exemption" issued under chapter 69.50 RCW.

(37) "Plan of correction" means a proposal devised by the applicant or licensee that includes specific actions that must be taken to correct identified unresolved deficiencies with the time frames to complete them.

(38) "Statement of deficiency" means a written statement of the deficiencies prepared by the commission, or its designee, identifying one or more violations of law. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

NEW SECTION. **Sec. 31.** A new section is added to chapter 18.64 RCW to read as follows:

This section governs the denial of an application for a license or the suspension, revocation, or modification of a license issued by the commission. This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission shall give written notice of the denial of an application for a license to the applicant or its agent. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(2) The commission shall give written notice of revocation, suspension, or modification of a license to the licensee or its

agent. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(3) Except as otherwise provided in this chapter, revocation, suspension, or modification is effective 28 days after the licensee or the agent receives the notice.

(a) The commission may make the date the action is effective later than 28 days after receipt. If the commission does so, it shall state the effective date in the written notice given to the licensee or its agent.

(b) The commission may make the date the action is effective sooner than 28 days after receipt when necessary to protect the public health, safety, or welfare. When the commission does so, it shall state the effective date and the reasons supporting the effective date in the written notice given to the licensee or its agent.

(4) Except for licensees suspended for noncompliance with a child support order under chapter 74.20A RCW, a license applicant or licensee who is aggrieved by a commission denial, revocation, suspension, or modification has the right to an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The form, contents, and service of the application for an adjudicative hearing must comply with this chapter and with the procedural rules adopted by the commission and must be served on and received by the commission within 28 days of the applicant or licensee receiving the notice.

(5)(a) If the commission gives a licensee 28 or more days' notice of revocation, suspension, or modification and the licensee files an appeal before its effective date, the commission shall not implement the adverse action until the final order has been entered. The commission may implement part or all of the adverse action while the proceedings are pending if the appellant causes an unreasonable delay in the proceeding, if the circumstances change so that implementation is in the public interest, or for other good cause.

(b) If the commission gives a licensee less than 28 days' notice of revocation, suspension, or modification and the licensee timely files a sufficient appeal, the commission may implement the adverse action on the effective date stated in the notice. The commission may stay implementation of part or all of the adverse action while the proceedings are pending if staying implementation is in the public interest or for other good cause.

(6) The commission may accept the surrender of the licensee's license. A licensee whose surrender has been accepted may not petition for reinstatement of its surrendered license.

NEW SECTION. **Sec. 32.** A new section is added to chapter 18.64 RCW to read as follows:

This section governs the assessment of a civil fine against a licensee issued by the commission. This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission shall give written notice to the licensee or its agent against whom it assesses a civil fine. The form, contents, and service of the notice shall comply with this chapter and the procedural rules adopted by the commission.

(2) The civil fine is due and payable 28 days after receipt by the licensee or its agent. The commission may make the date the fine is due later than 28 days after receipt by the licensee or its agent. When the commission does so, it shall state the date the fine is due in the written notice given to the licensee against whom it assesses the fine.

(3) The licensee against whom the commission assesses a civil fine has the right to an adjudicative proceeding. The proceeding is governed by the administrative procedure act, chapter 34.05 RCW. The form, contents, and service of the application for an adjudicative hearing must comply with this chapter and the procedural rules adopted by the commission and must be served on and received by the commission within 28 days of the licensee receiving the notice.

NEW SECTION. **Sec. 33.** A new section is added to chapter 18.64 RCW to read as follows:

This section does not govern actions taken under chapter 18.130 RCW.

(1) The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply with any state or federal statute or administrative rule regulating the license in question including, but not limited to, Title 69 RCW, this chapter, chapter 18.64A RCW, and administrative

rules adopted by the commission, except as otherwise limited in this section.

(a) When the commission determines a licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission, the commission may impose reasonable conditions on a license. Conditions may include correction within a specified amount of time, a directed plan of correction, training, or hiring a commission-approved consultant if the licensee cannot demonstrate to the commission that it has access to sufficient internal expertise. If the commission determines the violations constitute immediate jeopardy, the conditions may be imposed immediately in accordance with subsection (2)(b) of this section.

(b)(i) In accordance with the commission's authority under section 32 of this act, the commission may assess a civil fine of up to $10,000 per violation, not to exceed a total fine of $1,000,000, on a licensee when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(ii) Proceeds from these fines may only be used by the commission to provide training or technical assistance to licensees and to offset costs associated with licensing and enforcement.

(iii) The commission shall adopt in rules under this chapter to establish specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance.

(iv) If a licensee is aggrieved by the commission's action of assessing civil fines, the licensee has the right to appeal under section 32 of this act.

(c) The commission may restrict the ability of a licensee to engage in a specific service related to a violation by imposing a

limited stop service. This may only be done if the commission finds that noncompliance results in immediate jeopardy.

(i) Prior to imposing a limited stop service, the commission shall provide a licensee written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The licensee shall have 24 hours from notification to develop and implement a commission-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions that constitute immediate jeopardy are not verified by the commission as having been corrected within the same 24-hour period, the commission may issue the limited stop service.

(ii) When the commission imposes a limited stop service, the licensee may not provide the services subject to the limited stop service, unless otherwise allowed by the commission, until the limited stop service order is terminated.

(iii) The commission shall conduct a follow-up inspection within five business days or within the time period requested by the licensee if more than five business days is needed to verify the violation necessitating the limited stop service has been corrected.

(iv) The limited stop service shall be terminated when:

(A) The commission verifies the violation necessitating the limited stop service has been corrected or the commission determines that the licensee has taken intermediate action to address the immediate jeopardy; and

(B) The licensee establishes the ability to maintain correction of the violation previously found deficient.

(d) The commission may deny an application, or suspend, revoke, or modify a license.

(2)(a) Except as otherwise provided, sections 31 and 32 of this act govern notices of actions taken by the commission under subsection (1) of this section and provides the right to an adjudicative proceeding. Adjudicative proceedings and hearings under this section are governed by the administrative procedure act, chapter 34.05 RCW.

(b) When the commission determines a licensee's noncompliance results in immediate jeopardy, the commission may make the imposition of conditions on a licensee, a limited stop service, or the suspension or modification of a license effective immediately upon

receipt of the notice by the licensee, pending any adjudicative proceeding.

(i) When the commission makes the suspension or modification of a license or imposition of conditions on a license effective immediately, a licensee is entitled to a show cause hearing before a hearing panel of the commission within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice. At the show cause hearing the commission has the burden of demonstrating that more probably than not there is an immediate jeopardy.

(ii) At the show cause hearing, the commission may consider the notice and documents supporting the immediate imposition of conditions on a licensee, or the suspension or modification of a license, and the licensee's response, and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the commission shall provide the licensee with all documentation that supports the commission's immediate imposition of conditions on a licensee or suspension or modification of a license.

(iii) If the hearing panel of the commission determines there is no immediate jeopardy, the hearing panel of the commission may overturn the immediate suspension or modification of the license or immediate imposition of conditions.

(iv) If the hearing panel of the commission determines there is immediate jeopardy, the immediate suspension or modification of the license or immediate imposition of conditions shall remain in effect pending a full hearing.

(v) If the commission sustains the immediate suspension or modification of the license or immediate imposition of conditions, the licensee may request an expedited full hearing on the merits. A full hearing must be provided within 90 days of the licensee's request, unless otherwise stipulated by the parties.

(3) The commission may take action under subsection (1) of this section against a nonresident pharmacy for failure to comply with any requirement of RCW 18.64.350 through 18.64.400, conduct that caused injury to a resident of this state, or conduct that resulted in adverse action against the nonresident pharmacy by a federal agency or the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

(4) When the commission determines an alleged violation, if true, would constitute an immediate jeopardy, and the licensee fails to cooperate with the commission's investigation of such an alleged violation, the commission may impose an immediate limited stop service, immediate imposition of conditions, or immediate suspension or modification of a license.

(a) When the commission imposes an immediate limited stop service, immediate imposition of conditions, or immediate suspension or modification of a license for failure to cooperate, a licensee is entitled to a show cause hearing before a presiding officer within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate limited stop service, immediate imposition of conditions, or immediate suspension or modification of a license for failure to cooperate. At the show cause hearing the commission has the burden of demonstrating that more probably than not the alleged violation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the commission's investigation.

(b) At the show cause hearing, the presiding officer may consider the notice and documents supporting the immediate limited stop service, immediate imposition of conditions, or immediate suspension or modification of a license for failure to cooperate, and the licensee's response and shall provide the parties with an opportunity to provide documentary evidence and written testimony, and to be represented by counsel. Prior to the show cause hearing, the commission shall provide the licensee with all documentation that supports the commission's immediate action for failure to cooperate.

(c) If the presiding officer determines the alleged violation, if true, does not constitute an immediate jeopardy or determines that the licensee cooperated with the commission's investigation, the presiding officer may overturn the immediate action for failure to cooperate.

(d) If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy and the licensee failed to cooperate with the commission's investigation, the immediate action for failure to cooperate shall remain in effect pending a full hearing.

(e) If the presiding officer sustains the immediate action for failure to cooperate, the licensee may request an expedited full

hearing on the merits of the commission's action. A full hearing must be provided within 90 days of the licensee's request.

NEW SECTION. **Sec. 34.** A new section is added to chapter 18.64 RCW to read as follows:

This section does not govern actions taken under chapter 18.130 RCW.

(1) A licensee whose license has been suspended under this chapter may petition the commission for reinstatement after an interval as determined by the commission in the order. The commission shall hold hearings on the petition. The commission may deny the petition or may order reinstatement of the licensee's license. The commission may impose terms and conditions in the order of reinstatement.

(2) A licensee whose license has been suspended for noncompliance with a support order or visitation order under RCW 74.20A.320 may petition for reinstatement at any time by providing the commission a release issued by the department of social and health services stating that the person is in compliance with the order. If the person has continued to meet all other requirements for reinstatement during the suspension, the commission shall automatically reissue the person's license upon receipt of the release, and payment of a reinstatement fee, if any.

NEW SECTION. **Sec. 35.** A new section is added to chapter 18.64 RCW to read as follows:

The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 36. RCW 18.64.047 and 2013 c 19 s 10 are each amended to read as follows:

(1) Any itinerant vendor or any peddler of any nonprescription drug or preparation for the treatment of disease or injury, shall pay a registration fee determined by the secretary on a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280. The department may issue a registration to such vendor on an approved application made to the department.

(2) Any itinerant vendor or peddler who shall vend or sell, or offer to sell to the public any such nonprescription drug or

preparation without having registered to do so as provided in this section, is guilty of a misdemeanor and each sale or offer to sell shall constitute a separate offense.

(3) In event the registration fee remains unpaid on the date due, no renewal or new registration shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280. This registration shall not authorize the sale of legend drugs or controlled substances.

(4) An itinerant vendor may purchase products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The commission shall issue a warning to an itinerant vendor who violates this subsection, and may suspend or revoke the registration of the vendor for a subsequent violation.

(5) An itinerant vendor who has purchased products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:

(a) The itinerant vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ((~~ten~~)) 10 percent of the vendor's total prior monthly sales of nonprescription drugs in March through October. In November through February, the vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ((~~twenty~~)) 20 percent of the vendor's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. ((~~The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection.~~))

(b) The itinerant vendor shall maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the commission. The records must be available for

inspection by the commission or any law enforcement agency and must be maintained for two years. The commission may suspend or revoke the registration of an itinerant vendor who violates this subsection. For purposes of this subsection, "disposition" means the return of product to the wholesaler or distributor.

Sec. 37. RCW 18.64.165 and 2016 c 81 s 10 are each amended to read as follows:

((~~The commission shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor~~)) In addition to any other grounds, the commission may take action against a license issued under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW, except nonresident pharmacies, upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) Except as provided in RCW 9.97.020, the licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the commission or has been convicted of a felony.

Sec. 38. RCW 18.64A.020 and 2013 c 19 s 33 are each amended to read as follows:

(1)(a) The commission shall adopt, in accordance with chapter 34.05 RCW, rules fixing the classification and qualifications and the educational and training requirements for persons who may be employed as pharmacy technicians or who may be enrolled in any pharmacy technician training program. Such rules shall provide that:

(i) Licensed pharmacists shall supervise the training of pharmacy technicians;

(ii) Training programs shall assure the competence of pharmacy technicians to aid and assist pharmacy operations. Training programs shall consist of instruction and/or practical training; and

(iii) Pharmacy technicians shall complete continuing education requirements established in rule by the commission.

(b) Such rules may include successful completion of examinations for applicants for pharmacy technician certificates. If such examination rules are adopted, the commission shall prepare or

determine the nature of, and supervise the grading of the examinations. The commission may approve an examination prepared or administered by a private testing agency or association of licensing authorities.

(2) The commission may disapprove or revoke approval of any training program for failure to conform to commission rules. In the case of the disapproval or revocation of approval of a training program by the commission, a hearing shall be conducted in accordance with ((~~RCW 18.64.160~~)) section 31 of this act, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW.

Sec. 39. RCW 18.64A.060 and 2013 c 19 s 38 are each amended to read as follows:

No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission.

Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require.

The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with ((~~chapter 18.64 RCW, as now or hereafter amended,~~)) section 31 of this act and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW.

NEW SECTION. **Sec. 40.** A new section is added to chapter 69.38 RCW to read as follows:

Chapter 18.64 RCW governs the denial of licenses and the discipline of persons licensed under this chapter. The uniform

disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a license under this chapter.

Sec. 41. RCW 69.45.080 and 2013 c 19 s 84 are each amended to read as follows:

(1) The manufacturer is responsible for the actions and conduct of its representatives with regard to drug samples.

(2) ((~~The commission may hold a public hearing to examine a possible violation and may require a designated representative of the manufacturer to attend.~~

~~(3) If a manufacturer fails to comply with this chapter following notification by the commission, the commission may impose a civil penalty of up to five thousand dollars. The commission shall take no action to impose any civil penalty except pursuant to a hearing held in accordance with chapter 34.05 RCW.~~

~~(4)~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of persons registered under this chapter.

(3) Specific drug samples which are distributed in this state in violation of this chapter, following notification by the commission, shall be subject to seizure following the procedures set out in RCW 69.41.060.

NEW SECTION. **Sec. 42.** A new section is added to chapter 69.45 RCW to read as follows:

The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

Sec. 43. RCW 69.43.100 and 2013 c 19 s 74 are each amended to read as follows:

((~~The pharmacy quality assurance commission shall have the power to refuse, suspend, or revoke the permit of any manufacturer or wholesaler~~)) In addition to any other grounds, the pharmacy quality assurance commission may take action against a permit issued under this chapter upon proof that:

(1) The permit was procured through fraud, misrepresentation, or deceit;

(2) The permittee has violated or has permitted any employee to violate any of the laws of this state relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any

of the rules and regulations of the pharmacy quality assurance commission.

Sec. 44. RCW 69.43.140 and 2013 c 19 s 78 are each amended to read as follows:

(1) ((~~In addition to the other penalties provided for in this chapter or in chapter 18.64 RCW, the pharmacy quality assurance commission may impose a civil penalty, not to exceed ten thousand dollars for each violation, on any licensee or registrant who has failed to comply with this chapter or the rules adopted under this chapter. In the case of a continuing violation, every day the violation continues shall be considered a separate violation~~)) Chapter 18.64 RCW governs the denial of permits and the discipline of permits issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a permit under this chapter.

(2) The pharmacy quality assurance commission may waive ((~~the suspension or revocation of a license or registration~~)) action taken under chapter 18.64 RCW against a permit issued under this chapter ((~~18.64 RCW, or waive any civil penalty under this chapter,~~)) if the ((~~licensee or registrant~~)) permittee establishes that he or she acted in good faith to prevent violations of this chapter, and the violation occurred despite the licensee's or registrant's exercise of due diligence. In making such a determination, the pharmacy quality assurance commission may consider evidence that an employer trained employees on how to sell, transfer, or otherwise furnish substances specified in RCW 69.43.010(1) in accordance with applicable laws.

Sec. 45. RCW 69.50.302 and 2013 c 19 s 98 are each amended to read as follows:

(a) Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, shall obtain annually a registration issued by the ((~~department~~)) commission in accordance with the commission's rules.

(b) A person registered by the ((~~department~~)) commission under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to

the extent authorized by the registration and in conformity with this Article.

(c) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment. This exemption shall not include any agent or employee distributing sample controlled substances to practitioners without an order;

(2) A common or contract carrier or warehouse operator, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a substance included in Schedule V.

(d) The commission may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers upon finding it consistent with the public health and safety. Personal practitioners licensed or registered in the state of Washington under the respective professional licensing acts shall not be required to be registered under this chapter unless the specific exemption is denied pursuant to ((~~RCW 69.50.305~~)) sections 31 and 33 of this act for violation of any provisions of this chapter.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The department, at the direction of the commission, may inspect the establishment of a registrant or applicant for registration in accordance with rules adopted by the commission.

Sec. 46. RCW 69.50.303 and 2013 c 19 s 99 are each amended to read as follows:

(a) The ((~~department~~)) commission shall register an applicant to manufacture ((~~or~~)), distribute, dispense, or conduct research with controlled substances included in RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212 unless the commission determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the commission shall consider the following factors:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(2) compliance with applicable state and local law;

(3) promotion of technical advances in the art of manufacturing controlled substances and the development of new substances;

(4) any convictions of the applicant under any laws of another country or federal or state laws relating to any controlled substance;

(5) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels;

(6) furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

(7) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(8) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture or distribute controlled substances included in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered, or exempted under RCW 69.50.302(d), to dispense any controlled substances or to conduct research with controlled substances included in Schedules II through V if they are authorized to dispense or conduct research under the law of this state. The commission need not require separate registration under this Article for practitioners engaging in research with nonnarcotic substances included in Schedules II through V where the registrant is already registered under this Article in another capacity. Practitioners registered under federal law to conduct research with substances included in Schedule I may conduct research with substances included in Schedule I within this state upon furnishing the commission evidence of that federal registration.

(d) A manufacturer or distributor registered under the federal Controlled Substances Act, 21 U.S.C. Sec. 801 et seq., may submit a copy of the federal application as an application for registration as

a manufacturer or distributor under this section. The commission may require a manufacturer or distributor to submit information in addition to the application for registration under the federal act.

Sec. 47. RCW 69.50.304 and 2013 c 19 s 100 are each amended to read as follows:

(a) ((~~A~~)) This chapter and chapter 18.64 RCW govern the denial of registrations and the discipline of registrations issued under RCW 69.50.303. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

(b) In addition to any other grounds, the commission may take action against the registration, or exemption from registration, under RCW 69.50.303 to manufacture, distribute, ((~~or~~)) dispense, or conduct research with a controlled substance ((~~may be suspended or revoked by the commission~~)) upon finding that the registrant has:

(1) furnished false or fraudulent material information in any application filed under this chapter;

(2) been convicted of a felony under any state or federal law relating to any controlled substance;

(3) had the registrant's federal registration suspended or revoked and is no longer authorized by federal law to manufacture, distribute, ((~~or~~)) dispense, or conduct research with controlled substances; or

(4) committed acts that would render registration under RCW 69.50.303 inconsistent with the public interest as determined under that section.

((~~(b)~~)) (c) The commission may limit revocation or suspension of a registration to the particular controlled substance or schedule of controlled substances, with respect to which grounds for revocation or suspension exist.

((~~(c)~~)) (d) If the commission suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

((~~(d)~~)) (e) The ((~~department~~)) commission may seize or place under seal any controlled substance owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by the registration. The controlled substance must be held for the benefit of the registrant or the registrant's successor in interest. The ((~~department~~)) commission shall notify a registrant, or the registrant's successor in interest, who has any controlled substance seized or placed under seal, of the procedures to be followed to secure the return of the controlled substance and the conditions under which it will be returned. The ((~~department~~)) commission may not dispose of any controlled substance seized or placed under seal under this subsection until the expiration of ((~~one hundred eighty~~)) 180 days after the controlled substance was seized or placed under seal. The costs incurred by the ((~~department~~)) commission in seizing, placing under seal, maintaining custody, and disposing of any controlled substance under this subsection may be recovered from the registrant, any proceeds obtained from the disposition of the controlled substance, or from both. Any balance remaining after the costs have been recovered from the proceeds of any disposition must be delivered to the registrant or the registrant's successor in interest.

((~~(e)~~)) (f) The ((~~department~~)) commission shall promptly notify the drug enforcement administration of all orders restricting, suspending, or revoking registration and all forfeitures of controlled substances.

Sec. 48. RCW 69.50.310 and 2013 c 19 s 104 are each amended to read as follows:

On and after September 21, 1977, a humane society and animal control agency may apply to the ((~~department~~)) commission for registration pursuant to the applicable provisions of this chapter for the sole purpose of being authorized to purchase, possess, and administer sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals. Any agency so registered shall not permit a person to administer sodium pentobarbital unless such person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering this drug.

The ((~~department~~)) commission may issue a limited registration to carry out the provisions of this section. ((~~The commission shall~~

~~promulgate such rules as it deems necessary to insure strict compliance with the provisions of this section. The commission may suspend or revoke registration upon determination that the person administering sodium pentobarbital has not demonstrated adequate knowledge as herein provided. This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter.

Sec. 49. RCW 69.50.320 and 2013 c 19 s 106 are each amended to read as follows:

The department of fish and wildlife may apply to the ((~~department of health~~)) commission for registration pursuant to the applicable provisions of this chapter to purchase, possess, and administer controlled substances for use in chemical capture programs. The department of fish and wildlife must not permit a person to administer controlled substances unless the person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering controlled substances.

The ((~~department of health~~)) commission may issue a limited registration to carry out the provisions of this section. The commission may adopt rules to ensure strict compliance with the provisions of this section. The commission, in consultation with the department of fish and wildlife, must by rule add or remove additional controlled substances for use in chemical capture programs. ((~~The~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under this chapter. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, the commission ((~~shall~~)) may suspend or revoke a registration issued under this chapter upon determination that the person administering controlled substances has not demonstrated adequate knowledge as required by this section. ((~~This authority is granted in addition to any other power to suspend or revoke registration as provided by law.~~))

Sec. 50. RCW 69.41.080 and 2013 c 19 s 57 are each amended to read as follows:

Humane societies and animal control agencies registered with the ((~~pharmacy quality assurance~~)) commission under chapter 69.50 RCW and authorized to euthanize animals may purchase, possess, and administer approved legend drugs for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs. For the purposes of this section, "approved legend drugs" means those legend drugs designated by the commission by rule as being approved for use by such societies and agencies for animal sedating or capture and does not include any substance regulated under chapter 69.50 RCW. Any society or agency so registered shall not permit persons to administer any legend drugs unless such person has demonstrated to the satisfaction of the commission adequate knowledge of the potential hazards involved in and the proper techniques to be used in administering the drugs.

The commission shall promulgate rules to regulate the purchase, possession, and administration of legend drugs by such societies and agencies and to insure strict compliance with the provisions of this section. Such rules shall require that the storage, inventory control, administration, and recordkeeping for approved legend drugs conform to the standards adopted by the commission under chapter 69.50 RCW to regulate the use of controlled substances by such societies and agencies. ((~~The~~)) Chapter 18.64 RCW governs the denial of licenses and the discipline of registrations issued under chapter 69.50 RCW. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. In addition to any other grounds, the commission may suspend or revoke a registration issued under chapter 69.50 RCW upon a determination by the commission that the person administering legend drugs has not demonstrated adequate knowledge as herein provided. ((~~This authority is granted in addition to any other power to suspend or revoke a registration as provided by law.~~))

NEW SECTION. **Sec. 51.** The following acts or parts of acts are each repealed:

(1) RCW 18.64.200 (Refusal, suspension, and revocation of other licenses—Appeal procedure) and 2013 c 19 s 15, 1963 c 38 s 11, & 1909 c 213 s 11;

(2) RCW 18.64.390 (Nonresident pharmacies—Violations—Penalties) and 2013 c 19 s 23 & 1991 c 87 s 5; and

(3) RCW 69.50.305 (Procedure for denial, suspension, or revocation of registration) and 2013 c 19 s 101 & 1971 ex.s. c 308 s 69.50.305.

--- END ---

PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 19, 2022
TIME: 3:31 PM

WSR 23-01-113

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: WAC 246-945-178--Pharmacist Continuing Education and WAC 246-945-220 Pharmacy Technician--Continuing Education. The Pharmacy Quality Assurance Commission (commission) is proposing amending sections of Chapter 246-945 WAC relating to continuing education requirements to establish minimum standards for health equity CE training programs.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005; RCW 18.130.040; RCW 43.70.613

Reasons why rules on this subject may be needed and what they might accomplish: Engrossed Substitute Senate Bill 5229 (Chapter 276, Laws of 2021), codified as RCW 43.70.613, requires rulemaking authorities to establish health equity continuing education (CE). Per RCW 43.70.613(1), "each health profession licensed under Title 18 RCW subject to continuing education requirements." There are the two professions under the jurisdiction of the commission subject to CE requirements under Title 18 RCW: Pharmacists and Pharmacy Technicians. The department is responsible for conducting model rulemaking that, once complete, the commission can either adopt the minimum requirements or establish its own rulemaking pertaining to health equity training as an element of existing CE requirements. The commission's CE requirements must meet at a minimum the same requirements as the model rules. The commission must complete its rulemaking on this issue by January 1, 2024.

The purpose of health equity CE training is to develop skills among licensed health care personnel to "address structural factors, such as bias, racism, and poverty that manifest as health inequities" per RCW 43.70.613(3)(c). Establishing training requirements for Pharmacists and Pharmacy Technicians will help identify and address ongoing health inequities in Washington State and promote overall patient safety.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: None

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative Rule Making

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

	(If necessary)
Name: Joshua Munroe	Name:
Address: PO Box 47852, Olympia, WA 98504-7852	Address:
Phone: 360-236-2987	Phone:
Fax: 360-236-2901	Fax:
TTY: 711	TTY:
Email: PharmacyRules@doh.wa.gov	Email:
Web site:	Web site:
Other:	Other:

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: https://public.govdelivery.com/accounts/WADOH/subscriber/new. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."	
Date: December 19, 2022 **Name:** Teri Ferreira, RPh **Title:** Pharmacy Quality Assurance Chair	**Signature:**