January 28, 2022

Commission meeting materials

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
December 17, 2021 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order December 17, 2021, 9:10 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Ken Kenyon, PharmD, BCPS
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Ann Wolken, PharmD, RPh

Commission Member Absent:
Bonnie Bush, Public Member

Staff Members:
Margaret C Holm, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Heather Carter, AAG
Hope Kilbourne, Policy Analyst
Martin Pittioni, Director, OHP
Marlee O'Neill, Deputy Director, OILS
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacy Consultant
Irina Tiginyanu, Pharmacy Technician Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1. **Call to Order** Teri Ferreira, Chair ***Action***

   1.1 Meeting Agenda Approval – December 17, 2021

   MOTION: Craig Ritchie moved to approve the meeting agenda for December 17, 2021. Ken Kenyon, second. Motion carries, 12:0.

   1.2 Meeting Minutes Approval – October 22, 2021

   MOTION: Craig Ritchie moved to approve the minutes for September 2, 2021. Ken Kenyon, second. Motion carries, 12:0. Staff members will confirm commissioner attendance for voting count accuracy for the October 22, 2021 meeting.

2. **Consent Agenda** Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. ***Action item.***

2.1 National Precursor Log Exchange Monthly Dashboard-November

2.2 Pharmaceutical Firms Application Report
October 05, 2021, thru December 1, 2021– new and closed firms

2.3 Ancillary Utilization Plans Approval
2.3.1 Lake Chelan Community Hospital Pharmacy
2.3.2 Olympia Pharmacy
2.3.3 Seattle Childrens Forest
2.3.4 Amerita

2.4 Pharmacy Technician Training Program Approval
2.4.1 Yokes Pharmacy
2.4.2 Duvall Family Drugs

MOTION: Craig Ritchie moved to remove 2.3.4 Amerita to 2.5 for discussion and to approve the remaining consent agenda. William Hayes, second. Motion carries, 12:0.

2.5 Regular Agenda/Items Pulled from 2a. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3.4 Amerita

MOTION: Tim Lynch moved to tentatively approve Amerita's AUP and task staff to clarify with Amerita the checklist they are referencing in the AUP ("Washington State Department of Health 797 Checklist"). Craig Ritchie, second. Motion carries, 12:0.

3. Old Business – The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. ***Information/Action.***

3.1 Nonresident Pharmacy Directive: Approved list of recognized State inspections

Lindsay Trant informed the commission a few clarifying statements were added to this document (Illinois – approved while USP 800 is not enforced in Washington). Staff also reconfigured the categories of state inspection reports to help clarify the different state inspections that are approved based on whether the nonresident pharmacy applicant engages in compounding.

Additional discussion clarified that an inspection report conducted by the Florida Board of Pharmacy would be accepted if a nonresident pharmacy attests they do not engage in compounding. If the nonresident pharmacy does engage in compounding then they would need to submit an inspection report from another commission approved inspection program.

MOTION: Craig Ritchie moved to approve the December 17, 2021 list of non-resident pharmacy approved state inspections. Ken Kenyon, second. Motion carries, 12:0.

4. **New Business--** The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. ***Information/Action.***

4.1 FAQ on Inventory Requirement for Controlled Substance Registrant

Lindsay Trant informed the commission that currently the rule requires registrants to conduct the inventory on the anniversary of the registration issuance date. However, it may be difficult for a registrant to meet that requirement on the same exact date. The FAQ as drafted mirrors the requirement for the DEA. If approved, staff will post the FAQ and distribute through GovDelivery.

MOTION: Tim Lynch motioned to approve the FAQ as written. Ken Kenyon, second. Motion carries, 12:0.

4.2 Feedback on DOH Interpretive Statement: Electronic Communication of Controlled Substance Prescriptions to Pharmacies Unable to Receive Electronic Prescriptions

Nomi Peaks reported to the commission that tribal pharmacies using the Indian Health Services' Resource and Patient Management System (RPMS) are having difficulty implementing the electronic prescription requirement for controlled substances in RCW 69.50.312. Commission instructed staff that further clarification is needed on this issue before taking any action. Staff will investigate the legislative intent of RCW 69.50.312(2).

4.3 List and label request

MOTION: Craig Ritchie moved to approve the list and label request. William Hayes, second. Motion carries, 11:0, one abstains.

5. **Rules and Legislative Updates** - ***Information/Action.***

5.1 Reauthorize emergency rules deleting Epidiolex from Schedule V

MOTION: Ken Kenyon moved to approve refiling of the emergency rules deleting Epidiolex from Schedule V. Craig Ritchie, second. Motion carries, 12:0.

5.2 Reauthorize emergency rules on prescribing Schedule II's during COVID-19

MOTION: Craig Ritchie moved to approve refiling of the emergency rules on prescribing Schedule II's during COVID-19. Hawkins DeFrance, second. Motion carries, 11:0, one abstains.

5.3 Two-Year License Renewal Cycle Implementation

MOTION: Craig Ritchie moved to begin rulemaking on repealing CE rules 246-861 WAC and WAC 246.901-061. Ken Kenyon, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to rescind policy statement, "New WAC Supersedes Old WAC: Clarification of Rules Enforcement After July 1, 2020". Ken Kenyon, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to rescind guidance document, "Enforcement of Intern Registration Renewal Limit." Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to instruct staff to prepare a guidance document stating we are not enforcing chapter 246-861 WAC and WAC 246-901-061 because we are in the process of repealing them. Ken Kenyon, second. Motion carries, 12:0.

5.4 DOH Request Regarding Pharmacist Licensure Requirement for Executive Director.

The commission is in agreement that the Executive Director position for pharmacy should be required to be a licensed pharmacist. Martin Pittioni will take PQAC's feedback to DOH leadership.

6. **Open Forum** (10 minutes) - ***Information Only.*** The purpose of the open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled.

Immunization records:

Richard Molitor brought the following to the attention of the commission:

Immunization teams are encountering patients requesting COVID-19 booster shots. In the public sectors, but in particular for patients in adult family homes, patients do not have immunization records in the IIS system. We have been told contract pharmacies that vaccinated patients last January and February were not required to report these vaccinations or issue certificates of immunization. This has prompted questions by our staff of the CDTA protocol authorized by the medical director, booster shots should only be given to those who have received the initial series. However, with no online or written records, how do we confirm that we can administer boosters to these individuals? Additionally, I suspect this affects the statistical reporting of the vaccination status of state residents. When he contacted DOH for advice on how to proceed with this particular situation, he was told "contact your local county department of health" – and that's not been helpful either.

Jenny Arnold, WSPA, noted the nursing home administered shots though the federal long-term care program partnership were required to be reported to the registry. If you are seeing holes in that reporting data, they have realized misalignments between reporting and getting the information into the system. Please write to jenny@wsparx.org for further information or help. At this point, all we can do is take a person at their word and having a validated statement by the homes owners will help until this can be worked through.

Processing of new licenses: Cindy Wilson, pharmacist, MultiCare Health System, continues to experience delays with processing new licenses (facilities and people) as well as changes in licensures (facility address / name changes). What efforts are being made in credentialling to try to improve the turn-around time?

Martin Pittioni assured Cindy this issue has the attention of the entire division. There is a new interim director in place, additional staff is being hired, as well as developing a new action plan to correct this issue.

7. Commission Member Reports. *Information/Action.*

7.1 Commissioner Reports

- Budget Subcommittee report – Patrick Gallaher
    - Pharmacy ended 2019-2021 biennium with $1.4 million in the black.
    - Discussed keeping credentialing accountable
    - If a commissioner requests something that requires funding it begins with the executive director and final determination is at DOH level.
    - Two HELMS payments in June of 2022 and 2023. The budget projections show us still ahead at the next biennium.

Is there a plan for going back to neutral licensure rates? Martin Pittioni responded that this is reviewed on a regular basis.

7.2 Commissioners' open discussion related to items or issues relevant to commission business/pharmacy practice.

- **MOTION:** Tim Lynch moved to approve developing an FAQ stating: "FAQ question: Can a pharmacy or pharmacist supply naloxone to a behavioral health clinic that is not licensed by the department of health or to an individual who is not credentialed by department of health for substance use disorder treatment. The pharmacy commission will not take action on a pharmacist or a pharmacy for suppling naloxone for substance use disorder in support of SB 5195. In addition to supply naloxone to persons or entities that are not licensed or credentialed by department of health in support of said bill. Craig Ritchie, second. Motion carries, 12:0.

  Cite the actual RCW and cite examples.

- Ken Kenyon notes there have been significant increases in complaints and business operations in pharmacies, closures, long waits. Staff will develop a GovDelivery regarding safety of our patients using the points above.

- Tim, oral anti-viral therapeutics labeling. Lindsay will investigate further.

8. Staff Reports *Information/Action.*

8.1 Interim Executive Director – Margaret Holm - none

8.2 Interim Deputy Director – Lindsay Trant

8.2.1 2022 Legislative Update Calls
- Weekly Legislative Calls on Fridays through March 11.
- Craig Ritchie and William Hayes volunteered to attend Martin Pittioni's legislative calls Wednesday mornings.
- Potential draft legislation, still research to be done on this topic: would require pharmacies to provide translated directions for use and side effects on prescription labels in languages other than English when requested. Oregon and California have implemented similar requirements but taken very different approaches.

8.3 OILS Deputy Director – Marlee O'Neill
- Routine Inspections – GovDelivery sent out
- Staffing
  - Pharmacy inspection supervisor job posting will be out soon
  - Pharmacy inspector positions recruiting opening. Funded by the federal grant. An informal offer has been made to one candidate.
  - Staff attorney – OILS continuing to recruit for the vacant staff attorney positions.

8.4 Assistant Attorney General – Heather Carter – none

9. Summary of Meeting Action Items – Commissioner and staff will revisit action items identified during today's business meeting.

1.2 October minutes – Staff to confirm vote count vs number of panelists
2.3.4 AUPs – clarification needed on USP 797 check list reference
3.1 Nonresident pharmacy directive – post the updated directive on website and send via GovDelivery.
4.1 FAQ on controlled substance registrants – post the FAQ on website and send via GovDelivery.
4.2 E-prescribing interpretive statement – provided feedback to the department
4.3 Approve the list and label request
5.1 Refile Epidiolex emergency rules
5.2 Refile Emergency rules on prescribing CIIs during the COVID pandemic

5.3 Implementing two-year renewal cycle – initiate rulemaking to repeal old CE rules. Rescind the policy statement "new WAC supersedes old WAC"; resend the guidance document on the interim registration renewal limit and new guidance document that the old CE rules are not in effect while they are being repealed.

5.4 DOH request for pharmacist licensure requirement – Martin Pittioni will relay feedback to the department

7.2 Commissioner reports – publish FAQ on naloxone requirement and distribute via GovDelivery. Also send Gov Deliver on increased complaints we have received and sufficient staffing requirement under the new rules.

8 Staff Updates – convey back to the department that Craig and William will be joining the Wednesday calls with Martin.

12:16 p.m. **Business Meeting Adjourned.**

3.1

From: Appriss Health
To: [redacted]
Cc:
Subject: Washington NPLEx Dashboard Report - Dec 2021
Date: Saturday, January 1, 2022 3:43:29 AM
Attachments: WA_PHARMACY_TRX_REPORT_12012021.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

4 Logins - 0 Searches - 2 Report Queries - 28 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH

New Users = 0

Total Accounts = 141

Active Users = 3

TOP USAGE AGENCIES

1. Tukwila PD

TOP USERS BY USAGE

1. Trina Cook, Tukwila PD

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (16)

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	58,504	51,943	70,640	82,986	78,777	84,242	79,222	72,763	67,790	72,503	65,982	74,502	**859,854**
BLOCKS	2,433	2,301	2,931	3,933	3,515	3,763	3,233	2,899	2,952	2,947	2,491	2,971	**36,369**
GRAMS SOLD	130,934	117,632	165,200	197,654	185,979	198,842	181,384	164,623	151,157	158,114	142,705	159,271	**1,953,495**
BOXES SOLD	66,771	59,470	79,346	92,123	87,787	93,305	88,636	82,270	76,813	81,942	74,135	84,148	**966,746**
GRAMS BLOCKED	6,569	7,011	8,009	11,356	9,993	10,793	8,922	7,961	8,214	7,660	6,574	7,668	**100,730**
BOXES BLOCKED	2,700	2,897	3,183	4,360	3,929	4,110	3,617	3,324	3,487	3,288	2,872	3,336	**41,103**
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.60	2.54	2.63	2.47	2.40	2.36	2.33	2.29	2.30	**2.44**

PHARMACY PARTICIPATION STATISTICS (Dec 2021)

Enabled Pharmacies	998
Pharmacies Submitting a Transaction	944
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	54
Pharmacy Participation for Dec	94.59%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact kmccormick@appriss.com.

USP 800 825 SELF-INSPECTION WORKSHEET PUBLIC COMMENTS

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
					Regarding the USP 800 Self-Inspection Worksheet. I'm emailing regarding the requirement as a whole. It's important to have safe handling protocols in place when handling bulk hazardous drug product in a hospital or compounding pharmacy setting. However, there is very little contact at all in a traditional retail pharmacy. Can there be an exception to the requirement for traditional retail pharmacies that don't do any tablet manipulation of hazardous drugs?	Commission discrection
USP 825	Introduction	2	5		The question should be corrected to read "Are vial ~~septums~~ septa wiped with sterile 70% isopropyl alcohol prior to initial needle puncture~~s~~?" This language was purposely selected by the Expert Panel as evidenced by the language used later on "Wipe the septum with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple dose container)." There is not a required one-to-one correspondence between wiping the septa with a sterile 70% IPA swab and an aseptic insertion of a needle. The language should be corrected to reflect this distinction.	question comes from "Wipe the vial septum with sterile 70% isopropyl alcohol (IPA) prior to initial needle puncture." portion of citation; septa is the plueral of septum; agree that "initial" should be added
USP 825	Radiation Safety Considerations	3	6a		The question should be corrected to remove the typo; "Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of ~~theradioactive~~ the radioactive emissions"	agree
USP 825	Radiation Safety Considerations	4	9		This question should be deleted, ~~"Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?"~~ The issuance and wearing of dosimeters (whole body and rings) to record occupational radiation exposure of employees is regulated by the Radioactive Materials (RAM) License and has no place here. This language was included so BOP inspectors understand that nuclear pharmacists must wear body dosimeters and dosimeter rings (as required by their RAM license) under their gloves and to not consider them as they would consider regular jewelry rings.	citation is a continuation of 2.4, suggest adding the entire citation to to the self-inspection worksheet at the end of the current citation, portion in red refers to questions 9 & 10 "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."
USP 825	Radiation Safety Considerations	4	9		This question should be deleted, ~~"Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?"~~ The issuance and wearing of dosimeters (whole body and rings) to record occupational radiation exposure of employees is regulated by the Radioactive Materials (RAM) License and has no place here. This language was included so BOP inspectors understand that nuclear pharmacists must wear body dosimeters and dosimeter rings (as required by their RAM license) under their gloves and to not consider them as they would consider regular jewelry rings.	see above on line 6
USP 825	Immediate Use of Sterile Radiopharmaceuticals	4, 5, 6	Questions 11, 11a, 11b, 11c, 11d, 11f, 11g, 11h, 11i, 11j, 11k, 11l, 11m, 11m, 11n, 11o, 11p, 11q		This section on immediate use is not applicable to radiopharmacies because our RAM license prohibits us from injecting patients with radiopharmaceuticals. USP <825> states "This chapter applies to all practice settings where radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. Practice settings consist of state-licensed nuclear pharmacies, federal nuclear pharmacy facilities, and other healthcare facilities, including, but not limited to: nuclear medicine departments in hospitals and clinics, nuclear cardiology clinics (fixed site or mobile), and other specialty clinics." As radiopharmacies operate ISO classified cleanroom suites, or at a minimum SRPAs, they will not be preparing any sterile radiopharmaceuticals in ambient air, for immediate use and injection into a patient. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting
USP 825	Personnel Qualifications, Training, and Hygiene	12	45, 45a, 45b, 45c		As radiopharmacies operate ISO classified cleanroom suites, or at a minimum SRPAs, they will not be preparing any sterile radiopharmaceuticals in ambient air, for immediate use and injection into a patient. These questions should be deleted as they are only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
USP 825	Facilities and Engineering Controls	19	82		This question is incorrect because of a misquote. It should read; "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?" The direct quote from USP <825> is "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." I refer you to Table 7. Preparation Conditions for Sterile Radiopharmaceuticals which allows an "ISO Class 8 or better buffer area with ISO Class 8 or better ante-room" to achieve a 24 hour BUD or an "ISO Class 7 or better buffer area with ISO Class 8 or better ante-room to achieve a 96 hour BUD". Of the 4 verbs in the title of USP <825>, preparation including preparation with minor deviations, dispensing, and repackaging sterile radiopharmaceuticals may occur in an ISO Class 8 buffer area with an ISO Class 8 or better ante-room. Compounding, must occur in an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.	Commission discretion to add"If used to compound sterile radiopharmaceuticals" to the question to be more complete and reflect the citation
USP 825	Facilities and Engineering Controls	26	126		This question should be deleted, "~~Do all RAM users comply with the conditions specified in their approved RAM license application and regulations?~~" This paragraph explains that different facilities will have different RAM license requirements depending on the activities they perform, and radionuclides handled. Some facilities may require specific rooms and facilities to contain radioactive gasses and volatile compounds. An example is presented in the text.	question is pulled from the citation, the question does not differentiate the diffeences in facility type, only that the facility must comply with their approved RAM license applicaiton and regulations. citation as follows: "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."
USP 825	Assigning BUD	55, 56, 57	247, 247a, 247b, 247c, 247,d, 247e, 247f, 247g, 247h, 247i, 247j, 247k		Section 10.4 is a section that specifically deals with the radiolabeling of red blood cells that occurs in ambient air hence the title "10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use". As radiopharmacies operate under section 10.3 Preparation of Radiolabeled Blood Components with ISO Class 7 buffer rooms and ISO Class 8 ante rooms we will not be preparing any radiolabeled red blood cells in ambient air, for immediate use. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting
USP 825	Dispensing	61	269c, 269d		Question 269c should be a header for 269d. The patient name / identifier is only required for therapeutic and blood products.	suggest combining 269c and 269d to read:"For all therapeutic and blood-products, the patient name/identifier" to match citation
USP 825	Dispensing	62, 63, 64	271, 272, 272a, 272b, 273, 273a, 273b, 273c, 273d, 273e, 273f, 273g		This section is limited to the sterility and aseptic technique for direct infusion systems that infuse radiopharmaceuticals directly into patients. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting
USP 825					LETTER INTRO: The Nuclear & Precision Health Solutions (NPHS) Business of Cardinal Health is pleased to submit comments on the draft Washington Pharmacy Quality Assurance Commission Pharmacy Self-Inspection Worksheet for USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging addendum. In the spirit of full disclosure, I personally served on the Expert Panel that wrote USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging and am on the current USP Expert Panel on radiopharmaceuticals. I have the following comments. LETTER CONCLUSION: Cardinal Health can trace its lineage in the nuclear pharmacy industry back to the inception of centralized radiopharmacy practice in 1972. From that simple beginning, we have become one of the industry's leaders with 132 specialized radiopharmacies operating in 45 States, including radiopharmacies in Seattle and Spokane WA. Thank you again for allowing me to provide these comments on the proposed self-inspection form. If you would like to discuss any of the above comments, please feel free to contact me at 614-757-3174.	great comments, thank you for submitting them!
USP 800	List of Hazardous Drugs		Missing question based on requirements in the chapter	There is no question pertaining to the requirement of antineoplastic drugs and all HD API (table 1,2 or 3) requiring manipulation to follow all containment requirements within USP <800>.	I suggest an additional question to this section that asks " Do antineoplastic drugs requiring manipulation prior to administration and all HD API (NIOSH table 1, 2 and 3) follow all containment requirements defined in this chapter	no changes required; this is covered throughout the self-inspection document and USP 800
USP 800	List of Hazardous Drugs		4	This is incorrectly stated. NIOSH table 1 drugs (antineoplastics) requiring manipulation prior to administration and all HD API are not eligible for an assessment of risk for alternative containment strategies.	I suggest changing the questions to state " Is an assessment of risk performed on eligible hazardous drugs?" (NIOSH table 1 antineoplastics not requiring manipulation, table 2 and table3 hazardous drugs, not including any HD API)	no changes required; USP 800 box 1 outlines the requirments for hazardous drugs that can be determined from the assessment of risk for alternative containment strategies and work practices

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
USP 800	Facilities and Engineering Controls		20	Antineoplastic drugs in their final dosage forms can be stored with other non-HD inventory	I suggest changing this question to " Do you have all antineoplastic HDs requiring manipulation other than counting or repackaging and and all HD API stored separately from non-HDs?"	suggest rewording question to include qualifier from citation ("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.") suggest reworded question be: " Are all antineoplatic HDs requiring manipulation, other than counting or repackaging of final dosage forms, and any API HDs stored separately from non-HDs?"
USP 800	Facilities and Engineering Controls		31	C-PEC is incorrect. This should be the C-SEC maintains ISO 7. Additionally, this requires the ISO 7 classification to be maintained throughout the nonsterile compounding process, not just in general.	I suggest changing this question to "If compounding nonsterile and sterile HDs in the same room, is the C-SEC able to maintain ISO 7 classification continuously throughout the non-sterile compounding activities?"	agree that rewording the question is a better reflection of citation; suggest: "If compounding nonsterile and sterile HDs in the same room, is the nonsterile C-PEC effective to allow the room to maintain ISO 7 classification throughout the nonsterile compounding activity?" citation is: "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.
USP 800	Facilities and Engineering Controls		Missing question based on requirements in the chapter	Under the section for 5.3.2 Sterile Compounding, there are no engineering requirements listed, except in the next section for C-SCAs. I suggest outlining the requirements for an HD Buffer room for sterile compounding, which does have additional requirements other than what have been listed in the above sections.	+ I suggest adding these two sections in this area: - "If the C-PEC is in an ISO 7 buffer room with an adjacent ISO 7 ante room, are the following requirements met?:" - The C-PEC is externally vented - The C-SEC is externally vented - The C-SEC has HEPA filtered air supply - The C-SEC has a minimum of 30 ACPH - The C-SEC maintains a negative pressure between 0.01 and 0.03 inches of water column - The C-SEC maintains an air quality of IS0 Class 7 or better - A hand washing sink is located at in the ante room and is located at least 1 meter from the entrance into the HD buffer room - Both the anteroom and C-SEC have fixed walls + "If the C-PEC is located in an ISO 7 C-SEC with an ISO 7 ante room, does the room through which entry is made into the HD buffer room (e.g. ane room or non HD buffer room) meet the following requirements?": - Has a minimum of 30 ACPH of HEPA filtered supply air - Maintains a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas - Maintains an air quality of ISO Class 7 or better + I suggest editing #38, and combining #38 and #39, and adding an additional requirement regarding pass throughs. I recommend changing #38 to the following; - "If the negative pressure buffer room is entered through the positive pressure non-HD buffer room, are the following requirements met?" - A line of demarcation is defined in 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 room is used that minimizes the spread of HD contamination - A refrigerator pass-through is not used to transport HDs, HD CSPs, and HD waste in and out of the negative pressure buffer room	agree that questions are missing based on USP 800 content, reference citation is also missing; suggest adding the following questions and citation found in additional questions tab (added as questions 38-48, incorporating old questions 38 and 39 renumbered):
USP 800	Facilities and Engineering Controls		41		+ Per current version of USP <800>, the terms category 1 and category 2 are not used + This should be changed to match the current language in USP <800> to, " Are only low and medium-risk HD CSPs prepared in the C-SCA?"	Commission discretion, please advise which language should be used. the terms category 1 and category 2 in the 2019 version of USP 800 match the proposed USP 797. The USP 800 offical version, effective May 2020, using the terms low- and medium-risk to match the current version of USP 797 current citation in USP 800 effective May 2020: "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."
USP 800	Personal Protective Equipment		53		+The way this question is worded makes it seem like you would exit the C-SEC without any shoe covers on. I recommend changing this question to the following; -Is a second pair of shoe covers donned prior to entering the C-SEC and doffed upon exiting C-SEC?"	Commission discrection
USP 800	Receiving		71 and 73		These questions appear to be duplicative. I recommend removing #73	agree, question 73 is the same as question 71, except question 71 uses the same language as the citation

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
USP 800	Dispensing Final Dosage Forms		91		- This question is misleading. Per USP <800>, this restriction only applies to antineoplastic HDs, not all HDs. I suggest changing this question to the following: + "Does the facility not place antineoplastic HDs in automated counting or packaging machines?"	Commission discretion
USP 800	Deactivating, Decontaminating, Cleaning and Disinfecting		117		oThis requirement is specific to the work surface of a C-PEC. I suggest changing this question to the following; o"Are work surfaces of the C-PEC decontaminated between compounding different HDs?"	Commission discretion
USP 800	General Rule Reference				Is this worksheet's intent required for all pharmacies or just pharmacies that compound with hazardous products? In general, the form is very long and onerous for pharmacies that do not compound with hazardous products and would take away from patient care activities. If the intent is to address both compounding and traditional dispensing, I would suggest adding a question that asks if the pharmacy compounds and create a section for only the questions required for a pharmacy that does not compound.	Commission discretion
USP 800	List of Hazardous Drugs	2	4		The way the question is worded implies that all HDs need an assessment of risk. Propose to change the wording to "Did entity perform an assessment of risk?" and then use current question 5 ("If an assessment is not completed…") as a subpart of question 4. Also propose to add back to the USP reference "For dosage forms of other HDs on the NIOSH list, the entity may preform an assessment of risk to determine alternate containment strategies and work practices." to help clarify the question.	no changes required; USP 800 box 1 outlines the requirments for hazardous drugs that can be determined from the assessment of risk for alternative containment strategies and work practices
USP 800	Facilities and Engineering Controls	4	13		There is a typo in the question. Please correct "Do areas where HDs are handled have a hazard sign displayed before the entrance?".	agree; correct typo to read "Do areas where HDs are handled have a hazard sign displayed before the entrance?"
USP 800	Facilities and Engineering Controls	5	23		Propose to add "Does sterile or non-sterile compounding of HDs occur in a C-PEC located in a C-SEC?" to further clarify.	Commission discretion
USP 800	Receiving	14	71 and 73		These questions are duplicative. Please remove one.	agree, question 73 is the same as question 71, except question 71 uses the same language as the citation
USP 800	Dispensing Final Dosage Forms	17	91		This question is missing clarifying verbiage that is in the USP reference. Propose to make the changes "Does the entity ~~facility~~ not place antineoplastic HDs in automated counting or packaging machines?"	"facility" is used to align with language in rules; Commission discretion on addition of antineoplastic
USP 800	List of Hazardous Drugs	2	1		USP Reference column must be updated with USP 800 revision statement on July 1st, 2020. It was published on USP 43-NF38. It states: "For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list."	Commission discretion, please advise which language should be used. Language in the revised USP 800, that was changed in May 2020 and effective July 2020 reads: "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.▲ (RB 1-Jul-2020) 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....."
USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	9		This question introduces a new term "entity HD program" which may confuse stakeholders since the terminology introduction from the L&I WAC. Would recommend revision to just ask if the entity has a qualified and trained person responsible for oversight of the entity's hazardous drugs.	suggest changing entity to facility to align with Pharmacy rule language; the citation language indicates the designated individual is responsible for all aspects of the hazardous drug program (training, storage, environmental control, documentation) not just over the hazardous drugs, limiting the scope of the oversight in the question may not address the individual's full responsibility; citation: "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."
USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	10		Consider removing this question. The responsible manager filling out the form may not be the designated person in USP 800, so the answer to this question would be very subjective. It would be the same as asking if all personnel who handle HDs understand the same principles.	Commission discretion
USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	11		Consider expanding the question to include all responsibilities mentioned in the chapter: Is the DP responsible for all of the following: • Developing and implementing appropriate procedures • Overseeing entity compliance with chapter USP 800 and other applicable laws, regulations and standards, • Ensure competency of personnel, • Ensure environmental control of storage and compounding areas • Overseeing facility monitoring and maintaining reports of testing/sampling performed and acting on the results.	question is derived from a portion of the entire citation, elements mentioned are included in question 9 under "HD program". the citation question 11 is derived from is: "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."
USP 800	Facilities and Engineering Controls	5	20		Please specify that manipulation does not include counting and repackaging	please see line 18 above to address this comment

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
USP 800	Facilities and Engineering Controls	6	31		To add clarity that the ISO 7 classification is for the room (not the CPEC) please consider changing to say: If compounding sterile and non-sterile HDs in the same room, is the CPEC used for non-sterile compounding able to maintain ISO 7 classification of the room? In addition, please consider clarifying if sterile and non-sterile HD compounding can occur in the same Containment Segregated Compounded Area where the room does not have or need to maintain ISO7 classification.	please see line 19 above to address the first comment; Commission discretion on the second comment, question 31 is derived from the referenced citation, segregated compounding areas are discussed later in USP 800
USP 800	Facilities and Engineering Controls	6	34		To make it clear that manipulation does not include counting/repackaging please consider changing to say: Do C-PECs used for manipulation (not including counting/repackaging of tablets/capsules) of nonsterile HDs……	Commission discretion; additional wording left out of the question to conserve space and the individual completeing the self-inspection has the citation next to the question to reference
USP 800	Facilities and Engineering Controls	8	38 and 39		Nothing wrong with these two questions however the section USP 800 5.3.2 Sterile Compounding has more information that should be provided thru more questions. i.e. There should be a question similar to question 33: "Does the facility follow USP <797> for sterile compounding? There should also be some questions about the Engineering Controls Configurations (ISO Class 7 buffer room with an ISO Class 7 ante-room or the Unclassified C-SCA) and types of BSC appropriate for HD sterile compounding. In addition a question about what to do when sterile compounding non-HDs in a BSC used for HD compounding is needed as this is a scenario that is likely to occur in pharmacies and there is guidance on what to do in section 5.3.2 Sterile Compounding of USP 800.	see line 20 above
USP 800	Facilities and Engineering Controls	8	40-42		USP Reference column is referencing a section of USP 800 that was revised in on the newest prints of USP 800. In previous version of USP 800 it used to state: "Only Category 1 HD CSPs…."The most current version (as of July 1st, 2020 published in USP 43-NF28) states: "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 segregated compounding area."	see line above 21
USP 800	Facilities and Engineering Controls	8	41		See above comment. Consider changing the question to "Are only low and medium-risk HD CSPs prepared in the C-SCA?"	see line above 21
USP 800	Facilities and Engineering Controls	8	43		Consider removing this question. Administration of antineoplastics typically is not an activity performed by pharmacy personnel and as stated in the introduction of the worksheet, the self-inspection applies only to those activities performed by pharmacy personnel.	a facility can check N/A if appropriate to their setting
USP 800	Personal Protective Equipment	10	47e		Consider revision to "Outer gloves are changed every 30 minutes unless otherwise recommended….." to add clarity to the process and the requirement from USP.	citation does not specifiy outer gloves only chemotherapy gloves, citation: "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."
USP 800	Personal Protective Equipment	10	50		Consider adding clarity to this requirement as it may be taken out of context. "Clothing" means "Cloth laboratory coats, surgical scrubs, isolation gowns" as referenced in the previous paragraph of USP 800. If left as is it could also be interpreted as personal clothing which people may want to take home and properly wash if an accidental spill happened.	"clothing" is the language used in USP, an individual may reference the citation when completeing the self inspection, suggest updating citation to include entire citation (the portion in red was left out of the reference on the self-inspection): "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 of 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 not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.
USP 800	Personal Protective Equipment	12	57		Consider revision to : "Are outer chemotherapy gloves and sleeves covers carefully removed and discarded ….?" to add clarity to the USP 800 requirement. No ungloved hands should be inside a C-PEC so this requirement should only apply to the outer gloves. The inner gloves should be removed before leaving the C-SEC.	Commission discretion; language used in question is directly from USP 800

TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS
USP 800	Administering	17	97-103		Consider removing this section or asking more specifically; “Are HDs administered by pharmacy personnel in this facility? If yes continue to question 97. If no, skip to question 104. Administration is not activity usually performed by pharmacy personnel and not specifying whom the questions apply to would require the responsible manager to answer regarding other HCP activities (i.e. RNs).	Commission discretion; a facility can check N/A if appropriate to their setting
USP 800	Deactivating, Decontaminating, Cleaning and Disinfecting	20	115		Consider removing this question or revising to say: “If sodium hypochlorite is used as the deactivating agent, is there a neutralizing agent used afterwards to prevent corrosion?”. Again, not sure if this specific question is necessary since there are other EPA oxidizers with deactivation properties.	Commission discretion

WA Pharmacy Quality Assurance Commission

2021 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 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.

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 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						
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. 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 all 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 responsible for oversight of the entity's HD program?	**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 were 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	
			20.		Do you have antineoplastic and API HDs 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?	applicable safety precautions, such as secure shelves with raised front lips. 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 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	
			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		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			25.	Does the C-PEC operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding?	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 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 C-PEC able to maintain ISO 7 classification?		
			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.	If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, does it have a line of demarcation?	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING** Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also required: a line of demarcation must be defined	

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
			39.			If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, is there a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room that minimizes the spread of HD contamination?	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.	
			40.			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 Category 1 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.	
			40.	a		Fixed walls		
			40.	b		Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas		
			40.	c		Minimum of 12 ACPH		
			40.	d		Externally vented		
			40.	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.****		
			41.			Are only Category 1 HD CSPs prepared in the C-SCA?		
			42.			Do HD CSPs comply with the BUDs in <797> for CSPs prepared in a SCA?		
			43.			Are CSTDs used when administering antineoplastics?	**USP Chapter 800- 5.4 CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						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							
			44.	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.	
			45.	Is reusable PPE decontaminated and cleaned after use?			
			46.	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.	
			47.	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 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	
			47.	a	ASTM standard D6978		
			47.	b	Powder-free		
			47.	c	Inspected for defects before use		
			47.	d	Sterile outer gloves used when sterile compounding		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			47.	e	Changed every 30 minutes unless otherwise recommended by the manufacturer's documentation	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.	
			47.	f	Changed when torn, punctured, or contaminated		
			48.		Are hands washed with soap and water after removing gloves?		
			49.		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. 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 not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.	
			49.	a	Disposable		
			49.	b	Resist permeability by HDs		
			49.	c	Close in the back		
			49.	d	Long sleeved		
			49.	e	Closed cuffs that are elastic or knit		
			49.	f	Does not have seams or closures that could allow HDs to pass through		
			50.		Is potentially contaminated clothing not taken home under any circumstances?		
			51.		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.****		
			52.		Are gowns only worn in the HD handling areas?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			53.	Are two pairs of shoe covers only worn in 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.	
			54.	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.	
			55.	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.	
			56.	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					
			57.		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							
			58.		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.	
			59.		Does the entity have HD SOPs for the following:		
			59.	a	Labeling		
			59.	b	Transport		
			59.	c	Storage		
			59.	d	Disposal		
			59.	e	Use of Safety Data Sheets (SDS)		
			60.		Does the hazard communication program plan include the following:		
			60.	a	A written plan describing how the standard will be implemented		
			60.	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					
			60.	c	SDSs for each hazardous chemical used are readily available to personnel		
			60.	d	Information and training for personnel before initial assignment to work with a hazardous chemical and whenever the hazard changes		
			60.	e	Written confirmation from personnel of reproductive capability understanding the risks of handling HDs		
Personnel Training							
			61.		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.	
			62.		Does training occur before the employee independently handles HDs?		
			63.		Is effectiveness of training demonstrated by each employee?		
			64.		Is personnel competency reassessed at least every 12 months?		
			65.		Are personnel trained prior to the following:		
			65.	a	Introduction of a new HD		
			65.	b	Introduction of new equipment		
			65.	c	New or significant change in process or SOP		
			66.		Are all training and competency assessments documented?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			67.	Does the training include the following:			
			67.	a	Overview of entity's list of HDs and their risks		
			67.	b	Review of the entity's SOPs related to handling of HDs		
			67.	c	Proper use of PPE		
			67.	d	Proper use of equipment and devices		
			67.	e	Response to known or suspected HD exposure		
			67.	f	Spill management		
			67.	g	Proper disposal of HDs and trace-contaminated materials		
Receiving							
			68.	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 activity. Damaged packages or shipping cartons must be considered spills that must be reported to the designated	
			69.	Are HDs delivered to the HD storage area immediately after unpacking?			
			70.	Is PPE worn when unpacking HDs?			
			71.	Is a spill kit accessible in the receiving area?			
			72.	Does the entity enforce policies regarding HD receiving?			
			73.	Is a spill kit available in the receiving area?			
			74.	If a sterile compounding C-PEC is used when opening damaged shipping containers, is it disinfected after decontamination,			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				deactivation, and cleaning before returning to sterile compounding activity?		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.	
			75.	Are damaged packages or shipping cartons:			
			75.	a	Considered spills		
			75.	b	Reported to the designated person		
			75.	c	Managed according to the entity's SOPs		
			76.	Does clean-up comply with established SOPs?			
Labeling, Packaging, Transport and Disposal							
			77.	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.	
			77.	a	Labeling		
			77.	b	Packaging		
			77.	c	Transporting		
			77.	d	Disposal		
			78.	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.	
			79.	Do labeling processes prevent introduction of contamination in non-HD handling areas?			
			80.	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,	
			81.	Does packaging protect the HD product from damage, leakage,			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				contamination, and degradation during transport?	leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.	
			82.	Are there written SOPs for appropriate shipping containers and insulating materials?		
			83.	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.	
			84.	Are HDs transported in containers that minimize the risk of breakage or leakage?		
			85.	Does the entity not use pneumatic tubes to transport liquid or antineoplastic HDs?		
			86.	Does the entity consult the SDS when shipping HDs?		
			87.	Does the entity's HD labeling include storage, disposal, and HD category information consistent with the carrier's policies?		
			88.	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.	
			89.	Does HD disposal comply with all applicable regulations?		
Dispensing Final Dosage Forms						
			90.	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				
			91.	Does the facility not place HDs in automated 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						
			92.	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).	
			93.	Is compounding performed in proper engineering controls?		
			94.	Does the entity have equipment dedicated to HD compounding?		
			95.	Are bulk containers of liquid and API HD handled carefully to avoid spills?		
			96.	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 _____. If no, skip to question _____.						
Administering						
			97.	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				
			98.	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.	
			99.	Is PPE removed and disposed of in an approved HD waste container at the site of drug administration?		
			100.	Are equipment and packaging materials disposed of properly after administration?		
			101.	Are CSTDs used for administration of antineoplastic HDs when the dosage form allows?		
			102.	Are techniques and ancillary devices that minimize risk from open systems used when administering HDs through certain routes?		
			103.	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						
			104.	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	
			105.	Are sterile compounding areas and devices disinfected after cleaning?		
			106.	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				
			107.	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.	
			108.	Do written procedures for cleaning include procedures, agents used, dilutions (if used), frequency, and documentation requirements?		
			109.	Are personnel who perform deactivation, decontamination, cleaning, and disinfection in HD handling areas trained?		
			110.	Do personnel wear appropriate PPE?		
			111.	Are deactivating, decontaminating, cleaning, and disinfecting agents selected appropriate?		
			112.	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.	
			113.	Does the disposal of materials meet EPA regulations and the entity's policies?		
			114.	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				
			115.	Is a neutralizing agent used to remove the sodium hypochlorite?	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).	
			116.	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.	
			117.	Are work surfaces decontaminated between compounding different HDs?		
			118.	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?		
			119.	Are areas under the work tray deactivated, decontaminated, and cleaned at least monthly in the C-PEC?		
			120.	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.	
			121.	Are areas that are intended to be sterile disinfected?		
Spill Control						
			122.	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	
			123.	Are spills contained and cleaned immediately by qualified personnel with appropriate PPE?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			124.		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.	
			125.		Are signs available for restricting access to the spill area?		
			126.		Are spill kits readily available in all areas where HDs are routinely handled?		
			127.		If HDs are being prepared or administered in a non-routine healthcare area, is a spill kit and respirator available?		
			128.		Are spill materials disposed of as hazardous waste?		
			129.		Are the circumstances and management of spills documented?		
			130.		Do HD SOPs include the following:		
			130.	a	Spill prevention		
			130.	b	Direct the cleanup of spills		
			130.	c	Address the size and scope of the spill		
			130.	d	Specify who is responsible for spill management		
			130.	e	Type of PPE required		
			130.	f	Address the location of spill kits and clean-up materials		
			130.	g	Capacity of the spill kit		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Documentation and Standard Operating Procedures						
			131.	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.	
			132.	Are the SOPs reviewed at least every 12 months by the designated person?		
			133.	Is the SOP review documented?		
			134.	Are revisions in forms or records made as needed and communicated to all personnel handling HDs?		
			135.	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
2021 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 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 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 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."						
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 septums wiped with sterile 70% isopropyl alcohol prior to needle punctures?		

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 theradioactive 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					
			9.	Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?		Second Supplement to USP 42–NF 37 Physical Tests / á825ñ 3 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.	
			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 in an ambient environment that lacks primary and secondary engineering controls when intended for a single patient, are the following met:		**USP Chapter 825– 3 IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS** The preparation and dispensing of sterile radiopharmaceuticals in a patient care setting may be 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	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					deviations) components must be sterile, conventionally manufactured drug products.	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 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	
			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.		
			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.		
			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.		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			11.	l	Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area during the time of use.	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.	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 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	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			13.	Do personnel follow the policies and SOPs of the ANP or AU physician?	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.	
			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?		
			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:		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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 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	
			24.		Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?		
			25.		Do touch plates or other devices contain general microbial growth agar supplemented with neutralizing additives?		
			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?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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?		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.	
			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. 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.	
			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 as defined by the facility's policies and SOPs		
			31.	b	Performed with a commercial source of soybean–casein digest medium		
			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?			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			34.	Is the documentation maintained to provide a record and long-term assessment of personnel competency?		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.	
			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		
			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?			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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 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.	
			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?		
			43.	Are personnel who perform sterile compounding using a nonsterile drug substance or components 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	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						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 sterile 70% IPA. [NOTE—A different lab coat must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation.]	
			45.	a	Hand hygiene		
			45.	b	Garbing		
			45.	c	Different lab coat worn for patient care than 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 RadiopharmaceuticalProcessing 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	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			46.	f	Dry hands using low-lint towels	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 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	
			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		
			46.	k	Gloves completely and snugly cover the ends of the gown cuffs		
			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, donned items are properly disposed of		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			46.	q	New items are donned for reentry into the buffer area or SRPA	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).	
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	
			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.****		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			50.	Are results of the temperature and humidity readings documented at least once daily or stored in the continuous recording device, and retrievable?	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, maintained, monitored, and certified to have appropriate air quality.	
			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?		
			54.	Are temperature and humidity monitoring devices verified for accuracy at least every 12 months or as required by the manufacturer?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/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.****	**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 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	
			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?		
			61.	Is air supplied to classified areas introduced through HEPA filters located in the ceiling?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			66.	Is required garb worn prior to crossing the line of demarcation?	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 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	
			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?		
			71.	Is the SRPA not located adjacent to environmental control challenges?		
			72.	Are both pass-through doors never opened at the same time?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					the same time, which may be achieved using interlocking mechanisms.	
			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 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.	
			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?		
			78.	Are smoke studies 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**	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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.****	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 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. A dynamic airflow smoke pattern test must be performed initially and at least every 6 months to ensure that the PEC is properly	
			81.	Are PECs located out of traffic patterns and away from area air currents?		
			82.	Are PECs located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom?		
			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				
					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 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	
			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 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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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?	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.	
			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 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	
			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?		
			96.	Are walls constructed of or covered with a durable material?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			99.	Do floors include coving to the sidewall?	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.	
			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 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.	
			106.	Are overhangs or ledges easily cleanable?		
			107.	Is the facility where sterile radiopharmaceuticals are prepared designed so that activities 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	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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?	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 present. The sink must not be located inside the perimeter of the SRPA.	
			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?		
			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	
			114.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation promote effective cleaning and disinfecting?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			115.	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?	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.	
			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-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.	
			119.	Are food, drinks, and materials kept out of patient care, treatment areas, ante-rooms, and buffer areas?		
			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		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				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 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	
			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 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?		
			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				
					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.	
			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	
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			129.	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?	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 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	**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	

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
				general environment outside the classified areas?			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 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).	
			133.	a	Area surrounding the PEC may be ambient (unclassified) atmosphere			
			133.	b	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals			
			133.	c	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals			
			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	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			135.	Does certification of the classified areas, including PECs, include the following:		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.	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?			
			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	
			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		

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Yes	No	N/A					
					remained within the acceptable range	manufacturer; Monitoring of pressure differentials must be performed. See Packaging and Storage Requirements <659> for information on controlled area temperature and allowable excursions.	
			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 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.	
			141.		Are air and surface monitoring results and corrective actions documented?		
			142.		Are records readily retrievable?		
			143.		Does the microbiological air and surface monitoring program include viable impact volumetric airborne	**USP Chapter 825– 6.1 General Monitoring Requirements**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					particulate sampling and surface sampling?	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 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	
			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?		
			150.		Is sampling performed in the following circumstances:		
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			150.	e	In response to changes that could impact the controlled area environments	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 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	
			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:			
			151.	a	Diagram of the sampling locations		
			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		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			152.	Are air sampling devices serviced and calibrated as recommended by the manufacturer?	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 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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				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°–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	
			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.		
			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.		
			156.	e	Then incubate the inverted media at 20°–25° for no less than 5 additional days. Examine the media plates for growth.		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					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.	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.	
			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?		
			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		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				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, 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).	
			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 classification levels of the area sampled, is corrective action taken?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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 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	
			175.	Is each classified area sampled?		
			176.	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			179.	If the worker assesses that risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk?	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).	
			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 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	
			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?		
			184.	After sampling, is the sampled area cleaned and disinfected?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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.	
			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.	
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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?	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).	
			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						
			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	
			193.	If sterile processing of radiopharmaceuticals are not performed daily, is cleaning and disinfecting completed before initiating these activities?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			194.	Is reducing or removing radioactivity from an object or surface balanced with the risk of spreading radioactive contamination?	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 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.	
			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?		
			199.	Is cleaning performed in the direction of most to least clean areas?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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 Disinfectants and Antiseptics á1072ñ). 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.	
			206.	Is the disinfectant allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer without being disturbed?		
			207.	Is sterile 70% IPA used in the ISO Class 5 PEC?		
			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-	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			210.	Are disposable cleaning supplies discarded after each cleaning activity?	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).	
			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?		
			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	
			216.	Is the PEC wiped with a sporicidal agent at least monthly?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					activities. 6. The PEC must be 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?	**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 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.	
			218.	Are sporicidal or sterile disinfectant agents allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer?		
			219.	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		
			220.	Is each item transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant?		
			221.	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	
			222.	Is the critical site wiped ensuring that both chemical and mechanical		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				actions are used to remove contaminants?	remove contaminants. The sterile 70% IPA must be allowed to dry before piercing critical sites.	
			223.	Is sterile 70% IPA allowed to dry before piercing critical sites?		
			224.	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 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.	
			225.	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.****		
			226.	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						
			227.	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	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			228.	When assigning a BUD for a radiopharmaceutical(s), are the following considered:		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 peerreviewed literature. For compounded preparations (sterile and nonsterile), the 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	
			228.	a	Sterility		
			228.	b	Radiochemical purity where the assigned BUD is based on stability studies		
			228.	c	Radionuclidic purity		
			228.	d	Age of generator eluate		
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			228.	j	The assigned BUD of radiopharmaceuticals prepared from kits	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 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-	
			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				
					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. 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	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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 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						

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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; 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);	
			231.	a	Name of the radiopharmaceutical		
			231.	b	Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			231.	c	Detailed procedure	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 standard procedure; Container(s); Reference source of the BUD assignment and storage conditions.	
			231.	d	Range of radioactivity		
			231.	e	Range of volume		
			231.	f	Equipment to be used		
			231.	g	PEC and SEC to be used		
			231.	h	Quality control tests to be performed for final release of the radiopharmaceutical		
			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	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			232.	e	Reference to the MFR	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.	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		
			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	**USP Chapter 825– 10.2 Preparation with Minor Deviations** In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				same ingredients but may differ in their proportions?	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 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**	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			236.	Are blood sample preparations administered within 6 hours of receipt?	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 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	
			237.	Is there complete physical separation between where blood products are handled and non-blood products?		
			238.	Are blood products labeled in ISO Class 5 BSC in an ISO Class 7 buffer area?		
			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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			245.	Are all tubes and syringes in contact with patient blood components clearly labeled?	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, 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.	
			246.	Do SOP's address cleaning and disinfection process as required for blood-borne pathogens?		
			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**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			247.	a	A dedicated space for blood handling throughout the entirety of the blood radiolabeling process	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, 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.	b	Area free from clutter and not used for any other preparations or handling prior to cleaning and disinfection		
			247.	c	Only one procedure labeled at a time or a documented process to maintain integrity of samples and environment		
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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		
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,	**USP Chapter 825-11.1 Compounding Nonsterile Radiopharmaceuticals**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				and separated from sterile 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 (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	
			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?			
			256.	Are the ingredients obtained from the preferred sources?			
			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				
					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 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?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			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 pyrogenfree, a sterilization procedure (e.g., filtration with bubble point testing) and testing described in (85) must be performed. The designated 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.	
			264.	Does the designated person for compounding consider all possible interactions between components, such as stability, radiochemical stability, solubility, and other parameter?		
			265.	Does compounding of bulk drug substances comply with USP and NF monograph standards?		
			266.	Does compounding with excipients or other inactive ingredients comply with USP and NF monograph standards?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
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). The activity at calibration time must always be within federal, state, and local variance limits.	
			268.		Is the activity at calibration within 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	
			269.	a	Standard radiation symbol		
			269.	b	The words "Caution—Radioactive Material"		
			269.	c	For all therapeutic and blood-products		
			269.	d	The patient name/identifier		
			269.	e	Radionuclide and chemical form (generic name)		
			269.	f	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"		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			270.	c	For all therapeutic and blood-products, the patient name/identifier	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.	
			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		
			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.,	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					patients to reduce the radiation exposure to personnel	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-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.		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		
			273.	b	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table 7)		
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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		
			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	

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
							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 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	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			277.	c	Evaluation of complaints and adverse events	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 documented and appropriate corrective action taken, if needed.	
			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?		
			279.		Is the overall QA and QC program reviewed at least once every 12 months by the designated person?		
			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	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
					implementation and completion of the recall	regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (e.g., state board of pharmacy, state health department).	
			283.	b	Determine the distribution of any affected radiopharmaceutical, including the date and quantity		
			283.	c	Identify patients who have received the radiopharmaceutical		
			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,	
			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		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				extend to other radiopharmaceuticals?		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 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.	
			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?			
			292.	Does the record contain the following:			
			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			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				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 accordance with the facility's SOPs and all applicable laws and regulations?	**USP Chapter 825-14.3 Adverse Event Reporting** Adverse events potentially associated with the quality of radiopharmaceuticals must be reported in 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).	

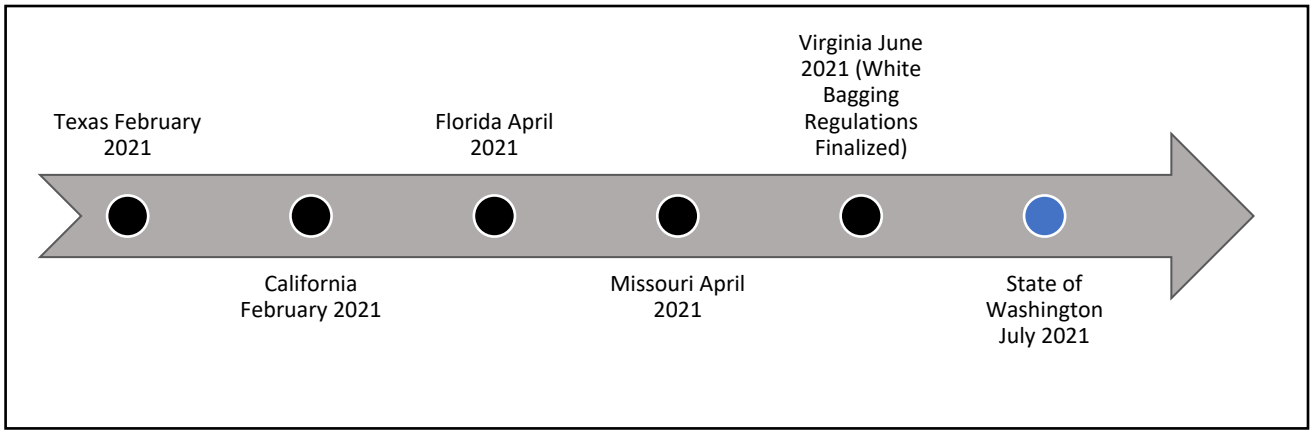
38. Does the facility follow <797> for sterile compounding?	In addition to this chapter, sterile compounding must follow standards in <797>. All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better 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 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.
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?	
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?	
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 facility has an ISO class 7 buffer room with an ISO class 7 ante-room:		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 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 though 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
	a. does the buffer room have HEPA-filtered supply air?	
	b. is the C-SEC externally vented?	
	c. does the buffer room have 30 ACPH?	
	d. does the buffer room have negative pressure between 0.01 and 0.03 of water column relative to adjacent areas?	
	e. does the ante-room have a minimum of 30 ACPH of HEPA-filtered supply air	
	f. does the ante-room maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas	
	g. does the ante-room maintain air quality of ISO Class 7 or better	
	h. does the ante-room have a hand-washing sink at least 1 meter from the entrance to the HD buffer room	

(old 38) 46. If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, does it have a line of demarcation?	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.
(old 39) 47. If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, is there a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room that minimizes the spread of HD contamination?	
48. Does the facility not use a refrigerated pass-through?	

WHITE BAGGING

State Boards of Pharmacy Discussions Related to Payer-Mandated White Bagging (2021)[1]



- **WA DOH PQAC Meeting July 16, 2021**
  - Presentation on white bagging by Mr. David Chen and Dr. Kyle Robb of American Society of Health-System Pharmacists (ASHP)
  - Motion carries for staff to conduct research on other states' rules/statutes regarding the topic of white bagging.
- **Payer-Mandated White Bagging Defined[2]**
  - Also known as white bagging.
  - Third-party specialty pharmacy is required by patient's insurance plan to buy and dispense medications that are administered by a clinician and are specific to the patient.
  - The medications ship directly from the specialty pharmacy to the clinician for administration.
  - Reimbursement for medication cost goes to the specialty pharmacy and reimbursement for medication administration goes to the clinician.
  - Distinguished from brown bagging and clear bagging.[3]

[1] Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.
[2] Data provided by Dr. Kyle Robb. ASHP. *How Boards of Pharmacy Are Addressing White and Brown Bagging*. Power Point presentation. Accessed October 22, 2021.
[3] Brown bagging involves a specialty pharmacy sending a medication to a patient directly, and the patient stores and transports the medication to the clinician for administration. Clear bagging reimburses a specialty pharmacy that is under shared common ownership with a clinician, for distributing patient-specific medications to that clinician, who is then reimbursed for administering the medications.

State Legislation Addressing Payer-Mandated White Bagging [4]

State	Legislation
• **Arkansas**	• Arkansas House Bill 1907
• **Louisiana**	• Louisiana Senate Bill 191
• **Massachusetts**	• Massachusetts Senate Docket 1808/ House Docket 3407 • Massachusetts Bill S.695/Bill H.1199[5,6]
• **New York**	• New York Senate Bill S7252[7]
• **Tennessee**	• Tennessee Senate Bill 1617
• **Texas**	• Texas House Bill 1586[8]
• **Virginia**	• Virginia House Bill 2219[9]

Arkansas	Louisiana	Massachusetts
• Arkansas House Bill 1907 • Effective Jan. 1, 2022 **Summary:** • Currently specific to patients with hematology or oncology diagnosis, or patients the insurance commissioner deems eligible. • A healthcare payer or pharmacy benefits carrier shall allow a healthcare provider to make "appropriate decisions that are in the best interest of patients." Payers cannot require a healthcare provider and patient to participate in white bagging if it is not in the best interest of the patient.[10]	• Louisiana Senate Bill 191 • Effective June 1, 2021 **Summary:** • White bagging must adhere to supply chain security controls established by the Drug Supply Chain and Security Act. • Insurance plans can deem a facility within their networks a "center of excellence" and create cost-sharing tiers to differentiate between those facilities that are centers of excellence and those that are not. • A healthcare payer or pharmacy benefits carrier shall not refuse payment to a participating provider for a physician-administered drug if the provider obtains the drug from a pharmacy that is not in the payer's network.[11]	• Mass. Senate Docket 1808/House Docket 3407 **Summary:** • White bagging allowed only for medications in "ready-to-administer" dosage form and whose pedigree had been certified prior to administration. • Any specialty pharmacy can distribute clinician-administered drugs that are covered by payer.[12] • Mass. S.695/H.1199 (pending) **Summary:** • Relative to specialty medications and patient safety. Recent hearing in September 2021 addressed concerns that white bagging may encourage poor medication adherence.[13]

[4] Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.
[5] Still pending as of October 22, 2021. Hearing held on September 21, 2021.
[6] Recording of hearing available at https://malegislature.gov/Events/Hearings/Detail/3966
[7] Still pending as of October 22, 2021.
[8] Died in Texas Senate in May 2021.
[9] Effective as of July 2021.
[10] HB1907 as engrossed on 04-22-2021 13:28:48 (state.ar.us)
[11] Bill Text: LA SB191 | 2021 | Regular Session | Chaptered | LegiScan
[12] MA - SD 1808 | GovHawk
[13] Bill S.695 (malegislature.gov)

New York	Tennessee	Texas	Virginia
• New York S7252 (pending) • Introduced June 2021. **Summary:** • Addresses patient safety and quality assurance related to patient-specific medications from insurer-designated pharmacies. • Calls for the provision of medication pedigree certification and use of ready-to-administer dosage form for white bagged, patient-specific medications.[14]	• Tennessee Senate Bill 1617 (amended) • Passed June 2021 **Summary**: • "Prohibits pharmacy benefits managers (PBMs) from charging unequal co-pays to patients for obtaining clinician-administered drugs between pharmacies that are contracted with the plan."[15,16]	• Texas House Bill 1586 • Final adjournment in May of 2021 (**died** in Texas Senate). • Amendment restricted the bill to apply specifically to patients with cancer-related diagnosis.[17]	• Virginia House Bill 2219 • Effective July 1, 2021 **Summary**: • Insurance plans cannot withhold coverage for medications that enrollees fill at non-affiliated pharmacies. These plans can also not place unequal cost burdens on patients who use out-of-network-pharmacies. • Requires "direct service agreements" between non-contracted pharmacies and insurance plans.[18] Related Virginia Board of Pharmacy Regulations are found in **18VAC110-20-275:** "One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law."[19]

Key Questions Regarding White Bagging[20]:

- How does white bagging impact patient safety?
- How would a pharmacy appropriately dispose of any unused portion of a white-bagged drug?

[14] S7252 (nysenate.gov)
[15] Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.
[16] Bill Text: TN SB1617 | 2021-2022 | 112th General Assembly | Chaptered | LegiScan
[17] Bill Text: TX HB1586 | 2021-2022 | 87th Legislature | Engrossed | LegiScan
[18] Bill Tracking - 2021 session > Legislation (virginia.gov)
[19] Virginia Regulatory Town Hall Show XML
[20] Data provided by Dr. Kyle Robb. ASHP. *Summary of Recent State Legislation to Address Payer Mandated White Bagging*. Power Point presentation. Accessed October 22, 2021.

- Will payers' motivations come at a cost to patients' financial benefits?
- Can a healthcare provider serve as a patient's agent when receiving medications?
- What about the distinction between dispensing and distributing [21 CFR 208.3(b)]?
- Can pharmacies re-label a white-bagged drug after its delivery but prior to its administration?
- What policies and procedures would be in place to ensure the integrity of white-bagged drugs?
- Is dispensing white-bagged pharmaceuticals considered repackaging?
- Should white bagging be addressed specifically in a facility's policies and procedures?
    - WAC 246-945-440: discusses the administration of patient owned medications.
- How might white bagging be impacted by the Drug Supply Chain Security Act product tracing requirements of 2023?
- Who will handle reimbursement rate challenges for pharmacies and medication administrators?

Commission SBAR Communication

Agenda Item/Title: Suspicious Order Requirements in WAC 246-945-585

Date SBAR Communication Prepared: January 20, 2022

Reviewer: Marlee O'Neill

Link to Action Plan:

☒ **Action** ☐ **Information** ☐ **Follow-up** ☐ **Report only**

Situation:

In its new rules, effective July 1, 2020, the commission adopted WAC 246-945-585 which, among other things, requires wholesalers to submit suspicious order reports. The commission exercised its enforcement discretion and did not find licensees deficient or take enforcement action against licensees for failure to comply with WAC 246-945-585(1)(a) through May 31, 2021.

Starting June 1, 2021, the commission began routinely receiving suspicious order reports. Since that time, commissioners and staff have realized there are challenges to implementing this rule. Wholesalers submit suspicious order reports in different formats (e.g., Excel spreadsheets, PDFs, etc) making it difficult for staff and commissioners to review, assess, and input the information. The number of suspicious orders reported by a wholesaler can be up to several hundred at a time. Wholesalers are reporting suspicious orders for drugs that are not controlled substances and not a drug of concern per commission rules such as Gabapentin. Wholesalers are not always reporting all the required information and, in one instance, cannot provide at one least piece of required data.

Background:
As part of the Commission's recent rules re-write, it adopted WAC 246-945-585 which was taken directly from NABP's Model Pharmacy Act/Rules. This rule does several things.

(1) requires wholesalers to design and operate a system that identifies and reports suspicious orders of controlled substances or drugs of concern and potential diversion to the Commission;
(2) sets requirements for what must be included in suspicious order or potential diversion reports;
(3) requires a wholesaler to submit a zero report if it identified no suspicious orders in a month;
(4) requires wholesalers to exercise due diligence in identifying suspicious orders and sets out what due diligence looks like;
(5) establishes when a wholesaler can sell controlled substances or drugs of concern to new customers; and
(6) establishes when a wholesaler can provide a suspicious order to existing customers.

The Commission adopted this rule recognizing that it would have to implement and carry out this rule with its existing resources. In addition, as with many new things, the Commission was aware that it may have to adjust over time as it gained experience with this rule.

At the June 3, 2021 business meeting, the commission voted to authorize rulemaking to amend WAC 246-945-585(1)(b) in order to modify the zero report submission requirement. The scope of this rulemaking did not include revisiting the suspicious order reporting requirement.

Assessment:
This rule was a new but important addition to the commission's new rules chapter. However, given the ongoing challenges experienced during implementation, commission staff suggest further examination of the rule is warranted.

Recommendation:
OPTION 1 (preferred): Commission staff recommends the commission task the facility subcommittee (Commissioners Kenyon, Ferreira, Hayes, Jung, and Lynch) with reviewing this rule and its implementation and preparing options and recommendations for the best way to proceed and presenting this at a future commission meeting.

OPTION 2: Instead of referring this work to the Facilities Subcommittee, the commission can consider action today. Available options include, but are not limited to, amending the scope of the previously authorized rulemaking on WAC 246-945-585 or directing staff to draft a guidance document or policy statement.

Follow-up Action:
Staff will proceed with steps as necessary to implement the commission's decision.

4.4

The Department of Health (DOH) is reaching out to individuals and communities who have experienced health inequities or racism in the health care system. Advocacy groups and health care professional associations are also invited.

This is an effort to learn how people are harmed due inequities in the health care system. We want to acknowledge its role in the health system. We want to create positive change in the health care system. Information we gather from listening sessions will be used in future rule workshops. Individuals, communities, and health care workers will work together to create rules for health equity continuing education. Health care professionals must complete trainings in health equity as required by Engrossed Substitute Senate Bill 5229.

DOH recognizes that sharing experiences about this subject may be difficult. We recognize and appreciate the emotional labor that will take place. We will make an intentional effort to create a safe space for participants and staff during this process. Sharing your experience is voluntary and it is up to you how you would like to share. If speaking in a group setting does not work for you, there is an option for written comments. No matter how you choose to take part, please know your willingness to engage in this process is greatly appreciated.

During these sessions, we will ask the following questions:

- What does health equity mean to you?
- What are your experiences with health inequities and how have they affected you?
- How can health care professionals improve so that they are providing fair healthcare?
- Is there anything else DOH needs to take into consideration?

To join us, use the link below. We will be holding listening sessions:

- Tuesday, February 1, 2022, from 5pm to 6pm via Microsoft Teams
- Thursday, February 10, 2022, from 10am to 11am via Microsoft Teams
- Tuesday, February 15, 2022, from 5pm to 6pm via Microsoft Teams
- Thursday, February 24, 2022, from 10am to 11am via Microsoft Teams

Microsoft Teams meeting
Join on your computer or mobile app
Click here to join the meeting
Or call in (audio only)
+1 564-999-2000,,114577531# United States, Olympia
Phone Conference ID: 114 577 531#

Please write us if you are unable to attend but want to share your experience. Written comments about past and current experiences with health inequities can be submitted via email to healthequityimplementation@doh.wa.gov. Please, do not hesitate to contact us with any questions, concerns, or comments.

Health Equity & ESSB 5229

What is Health Equity?

For the Washington State Department of Health (department), health equity exists when all people can attain their full health potential. That means people are not disadvantaged from achieving this potential because of the color of their skin, ancestry, level of education, gender identity, sexual orientation, age, religion, socioeconomic status, the job they have, the neighborhood they live in, or whether they have a disability.

Why do we need Health Equity?

Equity and equality are not the same. Equality gives everyone the same resources. Equity gives people the resources they need. With equity, everyone has the same opportunities as others. Research shows that inequities are part of the health care system. These have always existed. The COVID-19 pandemic has highlighted the different affects that people experience. This is because of discrimination and bias in the health care system. Access to health services and health care allows all families to enjoy productive and satisfying lives. Healthier Washingtonians lead to healthier, happier families and communities.

Washington State Department of Health

Contact Name
Ashley Bell
5229 Implementation Lead
Washington State Department of Health
healthequityimplementation@doh.wa.gov | 360-236-2961

What does Engrossed Substitute Senate Bill 5229 (ESSB 5229) do?

Providers – like doctors, nurses, and therapists – must take regular trainings called "continuing education." They take these to stay up to date in their field and learn about important and new topics relevant to their job. In 2021, the legislature passed a law that tells providers they must take continuing education courses on health equity. The training must teach about individual issues, system issues, and self-reflection. The goal is to help providers think about their own impact on the others. This can change how providers work with others and help reduce inequities.

How can you help?

We are reaching out to anyone who has experienced health inequities or racism in the health care system. The department will need help in the following ways:

Listening sessions – We will hold listening sessions with individuals and communities. We want to learn about your experiences with health inequities. We want to better understand how it harms individuals and be aware of its role in the health system. We need to recognize where the health system can transform. These sessions will be opportunities for us to hear from you.

Rule workshops – We will use what we hear in our listening sessions to lead our rules workshops. Workshops are where everyone comes together to create standards for health equity trainings. We will be working on draft language for the rules before we move into the formal comment period.

We value your input and want to listen to your experiences if you are willing to share. If you want to take or send us your stories, please email healthequityimplementation@doh.wa.gov.

5.1

Q: Should a label be affixed to a pre-drawn COVID-19 vaccine syringe? If so, what information should the label include?

A: It is important to appropriately label any pre-drawn syringe to minimize the risk of administration errors and vaccine mix-ups. This includes pre-drawn syringes of the COVID-19 vaccine. A label should be affixed to a syringe so that the markings on the barrel of the syringe are not obscured and pertinent label information is easily visible and legible. In keeping with WAC 246-945-018 and per guidance from the Centers for Disease Control and Prevention(CDC) and the United States Pharmacopeia(USP), best practices for pertinent label information include:

- The vaccine name and amount
- The expiration date and exact beyond-use date *and* time
- Lot number
- Initials of preparer(s)

At a minimum, the label should include the information specified in WAC 246-945-018. Other rules may be applicable under certain conditions.

While the CDC notes that the safest practice is to draw up a dose of COVID-19 vaccine immediately before administration, the WA Department of Health recognizes that there are circumstances in which the use of a pre-drawn syringe is necessary. Please consult the CDC website for current beyond-use dating for COVID-19 vaccines, and for further guidance related to storing and handling pre-drawn COVID-19 vaccine syringes.

Q: Should a label be affixed to a container used to transport pre-drawn COVID-19 vaccine syringes to mass vaccination clinics? Is so, what information should the label on the container include?

A: Per the CDC and the USP, both pre-drawn COVID-19 vaccine syringes and the containers used to store them during transport should be labeled. Best practices for labeling pre-drawn syringe storage containers include the following information:

- The name and phone number of the facility where the pre-drawn syringes were prepared
- Quantity of pre-drawn syringes in the container
- The vaccine name and amount
- The expiration date and exact beyond-use date *and* time
- Lot number
- Initials of the preparer(s)

To minimize vaccine mix-ups, containers used to store and transport pre-drawn COVID-19 vaccines must not be filled with multiple types of vaccines and affixed with multiple labels. For additional guidance related to transporting COVID-19 vaccines, please consult the CDC and the USP.

6.2

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 17, 2021
TIME: 7:39 AM

WSR 21-23-098

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. 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 21-15-108 filed on July 20, 2021. 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. Also, with the direction provided in RCW 69.41.010(15), the rules are being filed under the joint authority of the commission and the department.

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.

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:

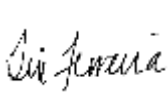
	New	10	Amended	0	Repealed	0

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: 09/02/2021	**Signature:**
Name: Teri Ferreira, RPh and Kristin Peterson, JD	 and 
Title: Pharmacy Quality Assurance Chair and Deputy Secretary, Policy and Planning	

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.

PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

In accordance with RCW 34.05.330, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at http://apps.leg.wa.gov/wac/default.aspx?cite=82-05.

CONTACT INFORMATION *(please type or print)*

Petitioner's Name _____

Name of Organization _____

Mailing Address _____

City _____ State _____ Zip Code _____

Telephone _____ Email _____

COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: _____

☐ **1. NEW RULE - I am requesting the agency to adopt a new rule.**

☐ The subject (or purpose) of this rule is: Make available translation of prescription directions of the label for prescriptions dispensed to ambulatory (community based) patients.

☐ The rule is needed because: Pharmacy software programs should support pharmacy professionals in providing safe care to patients with limited English proficiency. Software integration is essential for patient safety.

☐ The new rule would affect the following people or groups: Community pharmacies, patients and caregivers with limited English proficiency.

☐ **2. AMEND RULE - I am requesting the agency to change an existing rule.**

List rule number (WAC), if known: _____

☐ I am requesting the following change: Include (8) Pharmacy outpatient dispensing systems must have the ability to translate prescription medication directions by July 1st, 2025. Include subsections with details.

☐ This change is needed because: We need safe translation of instructions without the errors of overlay programs, cut and paste information and a tenable implementation date.

☐ The effect of this rule change will be: Reduce medication errors and increase adherence in patients with limited english proficiency in a safe and implementable way.

☐ The rule is not clearly or simply stated: We would also need details about exemptions (IV meds, LTC), English also on the label, which languages, "check labels" in English, transfers, etc.

☐ **3. REPEAL RULE - I am requesting the agency to eliminate an existing rule.**

List rule number (WAC), if known: _____

(Check one or more boxes)

☐ It does not do what it was intended to do.

☐ It is no longer needed because: _____

☐ It imposes unreasonable costs: _____

☐ The agency has no authority to make this rule: _____

☐ It is applied differently to public and private parties: _____

☐ It conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known: _____

☐ It duplicates another federal, state or local law or rule. List duplicate law or rule, if known: _____

☐ Other (please explain): _____