STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

PO Box 47852 – Olympia, Washington 98504-7852 – Tel: 360-236-4946 – TTY Relay: 800-833-6384

Pharmacy Quality Assurance Commission Meeting
December 14, 2023 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order on December 14, 2023, 9:01 AM.

Commission Members:
Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, PharmD, Nuclear Pharmacist, Vice Chair
Jerrie Allard, Public Member
Stephanie Bardin, PharmD, MA
Bonnie Bush, Public Member
Teri Ferreira, RPh
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Matthew Ray, PharmD
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh
Huey C. Yu, PharmD

Staff:
Shawna Fox, Office Director, Office of Health Professions
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, Assistant Attorney General
Kseniya Efremova, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant*
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Si Bui, Pharmacy Inspector Supervisor
Julia Katz, Program Consultant
Keith Bond, Operations Manager
Irina Tiginyanu, Pharmacy Technician Consultant
Amy L Robertson, Communications Coordinator and Program Support

*joined meeting at noon

1. Call to Order *Action*

1.1. Meeting Agenda Approval – December 14, 2023

MOTION: Craig Ritchie moved to approve the December 14, 2023, meeting agenda. William Hayes, second. Motion carries, 14:0.

1.2. Meeting Minutes Approval – October 19, 2023

MOTION: Craig Ritchie moved to approve the October 19, 2023, meeting minutes. William Hayes, second. Motion carries, 14:0.

1.3. Special Meeting Minutes Approval – November 13, 2023

MOTION: Craig Ritchie moved to approve the November 13, 2023, special meeting minutes. William Hayes, second. Motion carries, 14:0.

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.

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – October - November
2.1.2. Pharmaceutical Firms Application Report
2.1.3. Washington Association of Naturopathic Physicians Correspondence

2.2. Ancillary Utilization Plans Approval

2.2.1. Bob Johnson's Pharmacy
2.2.2. Cascade Specialty Pharmacy
2.2.3. Kaiser Permanente
2.2.4. Omnicare of Seattle
2.2.5. Spanaway Pharmacy
2.2.6. Sumas Drug
2.2.7. Sunnyside Pharmacy
2.2.8. Swedish Medical Center
2.2.9. Vashon Pharmacy
2.2.10. Vital Care of Tacoma
2.2.11. Virginia Mason

2.3. Pharmacy Technician Training Program Approval

2.3.1. Edmonds Community College
2.3.2. Moses Lake Professional Pharmacy
2.3.3. Yakima Valley Memorial Hospital

MOTION: Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.1.3, 2.2.1, 2.2.2, 2.2.5, 2.2.6, 2.2.7, 2.2.11, 2.3.1, and 2.3.2. Teri Ferreira, second. Motion carries, 14:0.

2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.2.3 Kaiser Permanente

MOTION: William Hayes moved to approve the 2.2.3 AUP contingent on clarification of item T27 to ensure it meets compliance with our guidance document on technician administration. Craig Ritchie, second. Motion carries, 14:0.

2.2.4 Omnicare of Seattle

MOTION: Teri Ferreira moved to approve the 2.2.4 AUP contingent on the removal of #6 and #13C in the assistant section as they are out of scope. Craig Ritchie, second. Motion carries, 14:0.

2.2.8 Swedish Medical Center

MOTION: William Hayes moved to approve 2.2.8 contingent on the removal of the outdated citation of WAC 246-901. Craig Ritchie, second. Motion carries, 14:0.

2.2.9 Vashon Pharmacy

MOTION: Teri Ferreira moved to approve 2.2.9 contingent on the removal of the last bullet on compounding in assistant section. Craig Ritchie, second. Motion carries, 14:0.

2.2.10 Vital Care of Tacoma

MOTION: William Hayes moved to approve 2.2.10 contingent on removing the outdated citations of chapters 246-871 and 246-878 WAC. Craig Ritchie, second. Motion carries, 14:0.

2.3.3 Yakima Valley Memorial Hospital

MOTION: Teri Ferreira moved to approve 2.3.3 contingent on the pharmacy adding the additional language commission notification and record retention. Craig Ritchie, second. Motion carries, 14:0.

3. Commission Member Reports

3.1. Budget Subcommittee Report – William Hayes reported the budget continues to be healthy. While the fund balance seems high, we expect this to come down over the next few years due to the commission being fully staffed. Commission payroll seems higher than normal because payouts from last biennium were not applied until this year. The forecast is positive with a projected end balance of $4,174,935. However, litigation is always unknown and may fluctuate. Staff are also monitoring the impact moving to a two-year renewal cycle will have on the budget.

4. Old Business

The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings.

4.1. Presentation from the Department's Office of Financial Services

Guests from the Office of Financial Services for the Department, Pam Ranes (Finance and Operations Manager) and Miceal Carnahan (Lead Finance Officer) presented on the process the department utilizes.

4.2. Presentation from the Board of Optometry Regarding SSB 5389

Kristina Bell (Program Manager, Board of Optometry) introduced members of the Board of Optometry (board). The board members and their staff presented draft changes to WAC 246-851-580, the codified drug list from which optometrists can prescribe.

- Bill Prothero, Optometrist (OD) - Former Chair
- Melissa Dacumos, Optometrist (OD) – Chair
- Riya Paranthan, Optometrist (OD)– Vice-Chair
- Theodore Kade, Optometrist (OD)

MOTION: Craig Ritchie moved to approve the medication list as proposed in WACs 246-851-580 and 246-851-590. Hawkins DeFrance, second. Motion carries, 14:0.

4.3. Revised USP Chapters and Nonresident Pharmacies

Taifa "Nomi" Peaks, Pharmacist Consultant, reminded the commission that in March 2023, the commission voted to begin enforcing the revised USP General Chapters <795>, <797>, and <800> in November 2023. This past year, the compounding subcommittee thoroughly reviewed and updated the directive, and the full commission voted to approve it this past summer. Because other boards of pharmacy may be in flux related to the enforcement of the revised USP <795> and <797>, and USP <800>, staff recommend that the commission start revisiting the directive in early 2024 with the hope that the full commission can adopt any revisions right after completion of the nonresident pharmacy renewal period in May 2024. This is because of the concern that approving a revised directive prior to that date could result in tremendous confusion for licensees and the potential for Washington residents not to receive their compounded medications from nonresident pharmacies in a timely fashion. In addition, all approved states have already been determined to at least be substantially equivalent to the former USP <795> and <797> chapters.

Commissioners discussed this and listened to stakeholder input. No action was taken.

4.4. Health Care Entity and 72-Hour Dispensing Limitation

Marlee O'Neill reviewed the draft FAQ regarding the 72-hour dispensing limitation for HCEs in RCW 18.64.450(4).

MOTION: Craig Ritchie moved to approve the FAQ as written. William Hayes, second. Motion carries, 14:0.

5. **New Business** The commission will review items of interest related to pharmacy practice for discussion, clarification, information, or action by or on behalf of the commission.

5.1. Pharmacy Intern Registration Renewal Limit

The commission received a question about WAC 246-945-155(3) pharmacist intern registration renewal limits at the October 2023 business meeting and asked to consider the topic at a future business meeting. The concern raised was that the two-renewal maximum makes it difficult for some pharmacy students to complete their internship hours before reaching the maximum renewal. An SBAR explaining the difference between previous and current rules about pharmacy internship renewal was included in the meeting materials.

5.2. Military Spouse Temporary Practice Permits for Pharmacy Interns

MOTION: Craig Ritchie moved to authorize staff to file a CR-101 on WACs 246-945-155, 246-945-156, and potentially adding a new WAC in chapter 246-945 WAC to consider changes to the commission's pharmacy intern registration limits and pharmacy intern temporary practice permit for military spouses. The motion also directed staff to draft a policy statement that allows pharmacy interns to request that the commission grant them more than the two renewals currently in rule and a policy statement that grants a 180-day temporary practice permit to military spouses seeking an intern registration. Teri Ferreria, second. Motion carries, 14:0.

6. **Panel Review** Study Plan (Panel B) – Hawkins DeFrance, Craig Ritche, Bonnie Bush, Matthew Ray, and Stephanie Bardin.

MOTION: Teri Ferreira moved to delegate the study plan reviews to Panel B: Hawkins DeFrance, Craig Ritchie, Bonnie Bush, Matthew Ray, and Stephanie Bardin. Teri Ferreira, second. Motion carries, 14:0.

6.1. PHRM.PH.61314899

MOTION: Craig Ritchie moved to approve the study plan review. Stephanie Bardin, second. Motion carries, 5:0.

6.2. PHRM.PH.61328969

MOTION: Bonnie Bush moved to approve the study plan review. Craig Ritchie, second. Motion carries, 5:0.

7. **Rules and Legislative Updates**

7.1. Significant Analysis Update: Accessible Labeling

Joshua Munroe provided an update on the accessible labeling rulemaking project.

7.2. Delegation of Commissioners for Weekly Office of Health Professions Legislative Call

MOTION: Teri Ferriera moved to delegate Hawkins DeFrance and Craig Ritchie to represent PQAC in the OHP legislative calls. William Hayes, second. Motion carries, 14:0.

7.3. Implementation Date for Health Equity Continuing Education

Joshua Munroe updated the commission on questions received from licensees on when they must comply with PQAC's health equity continuing education (CE) rule. The effective date for the CR-103p Rules Adoption package is 31 days after it is filed with the Code Reviser. Joshua explained that in August 2022, the commission voted that it will not take enforcement action and the department will not conduct CE audits until one full renewal cycle after October 27, 2022 (Reinstituting CE for Pharmacists and Pharmacy Technicians (govdelivery.com)). Even though the commission is not conducting continuing education audits, the commission does expect its licensees to comply with its CE rules. As a reminder, the department does have a list of free health equity CE trainings (Health Equity Continuing Education | Washington State Department of Health).

8. Presentations

8.1. Presentation from the Department's Legislative Team

Kelly Cooper, Director of Policy and Legislative Relations for the Department of Health, and Christie Spice, Deputy Assistant Secretary of Policy for the Health Systems Quality Assurance (HSQA) Division presented information on agency request legislation for the 2024 legislative session.

8.2. Presentation from the Office of Investigative and Legal Services

Judie Morton, Office Director for the Office of Investigative and Legal Services, Rayne Pearson, Deputy Director for the Office of Investigative and Legal Services, and Margaret Pagel, Supervising Staff Attorney for the Office of Investigative and Legal Services updated the commission on the work it does for the commission.

9. Rules and Legislative Updates

9.1. CR-103E: Refile Request for Medication Assistance

MOTION: Craig Ritchie moved to authorize the re-filing of the CR-103E on medication assistance because there is an emergent need for this rule to be extended for the health and safety of the public. William Hayes, second. Motion carries, 14:0.

9.2. Rules Workshop: Medication Assistance

Joshua Munroe reviewed the proposed rules for the commission regarding medication assistance. Marlee O'Neill reviewed feedback received on the draft rules.
Staff will revise the rules based on the commission's discussion and hold another rules workshop at an upcoming business meeting.

9.3. Rules Workshop: Adding Certain Intramammary Antibiotics (WAC 246-945-507)

MOTION: Craig Ritchie moved to approve the rule language as presented and authorized staff to file a CR-102 on WAC 246-945-507. Hawkins DeFrance, second. Motion carries, 14:0.

9.4. Rules Petition Request: Patient Notification Requirements for Pharmacy Closures

MOTION: Craig Ritchie moved to approve the petition and task staff with filing a CR-101 Rules Inquiry package on WAC 246-945-480. Patrick Gallaher, second. Motion carries, 14:0.

9.5. Rules Petition Request: Pharmacists Continuing Education

MOTION: Ken Kenyon moved to deny the petition because RCW 18.64.005(8) requires the commission to adopt rules establishing and governing continuing education requirements for its licensees and the commission cannot delegate its authority. Also, Washington law requires pharmacists to complete continuing education in certain areas such as suicide assessment and health equity and the Commission cannot waive these requirements. The petition only benefits a limited group of licensees and does not prevent these licensees from maintaining BPS certification. Finally, the commission understands that some educational materials completed as part of BPS's certification is ACPE accredited so pharmacists may already be able to use this toward the CE required in WAC 246-945-178. Craig Ritchie, second. Motion carries, 14:0.

10. **Open Forum** – none.

11. **Summary of Meeting Action Items** Commissioners and staff will revisit action items identified during today's business meeting.

2. Consent Agenda
   - Follow up with approvals and contingent approvals as directed by the commission.

4.1 Presentation from Office of Financial Services
- Add tracking/accounting for HELMS and have a line item for that in budget report.
- Circle back on credentialing line item as we would expect eventual decrease with transition to 2-year renewal cycle.
- Host a presentation from the Office of Financial Services at least yearly moving forward.

4.3 Revised USP Chapter Nonresident Pharmacies
- Staff will begin review of nonresident pharmacy directive with the compounding subcommittee early next year.

4.4 HCE and 72-Hour Dispensing Limitation
- Post the approved FAQs to the commission's website and distribute through GovDelivery

5.1 and 5.2 Pharmacy Intern Registration Renewal Limit – Military Spouse Temporary Practice Permits for Pharmacy Interns

- File a CR-101 on WACs 246-945-155, 246-945-156, and potentially adding a new WAC in chapter 246-945 WAC to consider changes to the commission's pharmacy intern registration duration and pharmacy intern temporary practice permit.
- Draft interim policy to allow students to petition commission to exceed the two-renewal limit on intern registrations also allowing military spouses to hold a temporary practice permit for 180-days and bring to a future business meeting for review.

6 Panel Review
- Communicate study plan approvals to credentialing.

7.2 OHP Weekly Legislative Calls
- inform OHP Hawkins DeFrance and Craig Ritchie will represent PQAC.

9.1 Emergency Rules Medication Assistance
- Refile emergency rule on medication assistance

9.2 Medication Assistance Rules Workshop
- Make suggested edits to the rule language reviewed today. Bring back to a future commission meeting for another rules workshop.

9.3 Adding Certain Intramammary Antibiotics Rules Workshop
- File CR-102 on the updated list on the approved legend drugs and controlled substances for use by the WDFW chemical capture program

9.4 Rules Petition: Patient Notification Closures Send petition approval letter
- File CR-101 to amend WAC 246-945-480 related to patient notification requirements for facility closures.

9.5 Rules Petition: Pharmacists CE
- Send petition denial letter due to the reasons stated at today's meeting.

Business Meeting Adjourned at 3:01 p.m.

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
December 15, 2023 - Minutes

Convene: Chair, Ken Kenyon called the meeting to order December 15, 2023, 9:11 AM.

Commission Members:
Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair
Teri Ferreira, RPh
Jerrie Allard, Public Member
Uyen Thorstensen, CPhT
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh
Huey Yu, PharmD
Stephanie Bardin, PharmD
William Hayes, PharmD CCHP
Bonnie Bush, Public Member

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Kseniya Policy Analyst
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Julia Katz, Program Consultant
Keith Bond, Operations Manager
Amy L Robertson, Communications Coordinator and Program Support

Commission Members Absent:

1. **Call to Order -** Ken Kenyon, Chair.

   1.1 Meeting Agenda Approval – December 15, 2023.

   MOTION: Craig Ritchie moved to approve the December 15, 2023, meeting agenda. Huey Yu, seconded. Motion carried, 14:0.

2. **Request for Consideration.**

   2.1 Collaboration Request for Midwifery Program Rules.

   Jennifer Santiago, Executive Director for the Midwifery Program, Kristin Effland, LM, Dr. Deb Gleisner, ND, LM (naturopath and licensed midwife), Katherine Sauerlender, LM, and Amber Ulvenes presented the midwifery program's draft rule to the commission for consultation. No action was taken by the commission.

3. Old Business.

3.1 Presentation on Lobbying from a Commissioner Perspective and the Public Records Act.

Christopher Gerard, AAG, led presentations on lobbying from a commissioner perspective and on the Public Records Act, RCW 42.56.

3.2 Repeal Policy Statement on Regulatory Standards Applicable to Remote Dispensing Sites.

MOTION: Craig Ritchie moved to repeal the policy statement on Regulatory Standards Applicable to Remote Dispensing Sites once the rule becomes effective. Huey Yu, seconded. Motion carried, 14:0.

3.3 Review Edits to Commission Bylaws.

MOTION: Craig Ritchie moved to approve bylaws contingent upon proposed edits to Article IV – Officers, number 5 Removal/replacement of Officer Positions to strike "a quorum of". Huey Yu, seconded. Motion carried, 14:0.

3.4 Continue Strategic Planning.

Keegan Curry provided a recap of prior strategic planning sessions and facilitated the next phase of planning.

4. New Business.

4.1 List and Labels Request.

MOTION: Craig Ritchie moved to recognize the Institute of Brain Potential as an educational organization. Huey Yu, seconded. Motion carried, 13:0:1. (Matthew Ray – Abstain.)

4.2 Regulations on Telepharmacy and Remote Supervision.

Commissioners discussed WAC 246-945-315 and other regulations relevant to telepharmacy and the remote supervision of ancillary staff and heard comments from stakeholders.

MOTION: Craig Ritchie moved to task staff with researching what other states are doing related to the regulation of telepharmacy and remote supervision, and presenting their findings to the commission at a future business meeting where appropriate in the next 3-6 months. Hawkins DeFrance, seconded. Motion carried, 14:0.

4.3 Pharmacy Technician Final Product Verification.

Commissioners discussed pharmacy technician final product verification and heard comments from stakeholders.

MOTION: Ken Kenyon moved to task staff with further analysis of whether final product verification is within the scope of practice for a pharmacy technician. Teri Ferreira, seconded. Motion carried, 14:0.

5. Ancillary Utilization Plan.

5.1 **Bellegrove Pharmacy.**

MOTION: Craig Ritchie moved to table a decision on the updated AUP. Teri Ferreira, seconded. Motion carried, 14:0.

6. Legislative Bill Report.

Joshua Munroe presented the PQAC legislative bill report.

MOTION: Craig Ritchie moved to express opposition to HB 1909. Hawkins DeFrance, seconded. Motion carried, 12:1:1. (Patrick Gallaher – Nay, Bonnie Bush – Abstain.)

7. Commission Member Reports. Open discussion related to items or issues relevant to commission business/pharmacy practice.

7.1 Ken Kenyon reported out on the 2023 NABP in Jackson, Wyoming. He informed the commission that Washington will be hosting the 2026 District 6, 7, & 8 meeting.

8. Staff Reports.

8.1 **Executive Director – Marlee O'Neill.**

- Marlee attended the November Board of Nursing (WABON) meeting as part of a panel discussion with the executive directors for the Washington Medical Commission and Chiropractic Quality Assurance Commission. The panelists spoke to the make-up of their respective commissions, its priorities, and how the commissions can work with WABON.
- Marlee and Si presented at the WSPA Annual Meeting in early November.
- Later in November, Marlee presented to the Southwest Washington Pharmacy Assoocation and Inspector Stephanie Martin joined her.
- Marlee thanked staff for their hard work, dedication and can-do attitude.

8.2 **Deputy Director – Lindsay Trant-Sinclair.**

- Lindsay provided the commission with a reminder to complete the Culture on Military Spouse Training by the end of the year.

8.3 **Pharmacist Supervisor – Si Bui.**

- Si informed the commission that the newest inspector, Justin Sisney, has completed training and is working in the field.

8.4 **Pharmacist Consultant – Taifa 'Nomi' Peaks.**

- Nothing to report.

8.5 **Assistant Attorney General – Christopher Gerard.**

- Nothing to report.

9. Summary of Meeting Action Items.

3.1 Presentation on Lobbying from a Commissioner Perspective and Public Records Act

- Staff will do additional research regarding email retention, retention schedules, and statutory lobbying restrictions and how those apply to talking with stakeholder groups.

3.2 Repeal Policy Statement on Regulatory Standards Applicable to Remote Dispensing Sites

- Repeal policy statement on remote dispensing sites for opioid use disorder medications once rule becomes effective.

3.3 Bylaws

- Staff will finalize the bylaws and distribute them to the commissioners and post them to box.com. Note: The nonresident pharmacy directive task force will consist of Hawkins, Uyen, Ann, and Huey, with Hawkins as the chair. Staff will work with the task force on next steps and schedule task force meetings.

3.4 Strategic Planning

- Staff will continue to refine the objectives in the operational and licensing efficiencies goal based on commissioner feedback today and bring a final draft of the strategic plan to the commission at a future business meeting.

4.1 List and Label Request

- Communicate the commission's decision to the department's public disclosure unit.

4.2 Regulations on Telepharmacy and Remote Supervision

- Staff will review what other states and Canadian provinces are doing related to the regulation of telepharmacy and remote supervision and will present the research at future business meeting.

4.3 Pharmacy Technician Final Product Verification

- Staff will conduct a legal review on the commission's authority around pharmacy technician final product verification, including an analysis of discretionary tasks.

6. Legislative Bill Report

- Communicate the commission's opposition on HB 1909 to the department.

Business Meeting Adjourned at 3:30 p.m.

2.1.1. National Precursor Log Exchange Monthly Dashboard – December

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (32)
Total Accounts = 144		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	71,650	69,842	81,463	75,970	78,412	79,249	64,423	60,350	71,428	70,893	70,043	79,650	**873,373**
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	3,003	3,960	3,090	3,278	**41,691**
GRAMS SOLD	149,571	145,519	177,064	166,664	180,078	181,015	147,213	134,301	150,884	147,981	145,274	162,032	**1,887,596**
BOXES SOLD	81,434	79,115	91,959	86,273	88,279	89,812	73,523	68,692	79,937	79,777	77,725	88,010	**984,536**
GRAMS BLOCKED	8,604	8,664	10,706	9,791	11,005	11,827	8,815	7,283	7,872	10,941	8,163	8,820	**112,491**
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	3,557	4,420	3,446	3,877	**47,765**
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	2.21	2.48	2.37	2.27	**2.35**

PHARMACY PARTICIPATION STATISTICS (Dec 2023)

Enabled Pharmacies	966
Pharmacies Submitting a Transaction	888
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	78
Pharmacy Participation for Dec	91.93%

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 krista.mccormick@equifax.com.

2.1.2. Pharmaceutical Firms Application Report

Credential #	Status	First Issuance Date
DRSD.FX.61483700	ACTIVE	12/04/2023
DRSD.FX.61510617	ACTIVE	12/04/2023
PHNR.FO.61503483	ACTIVE	12/04/2023
PHNR.FO.61503514	ACTIVE	12/04/2023
PHNR.FO.61511292	ACTIVE	12/04/2023
PHNR.FO.61508199	ACTIVE	12/04/2023
PHNR.FO.61502663	ACTIVE	12/04/2023
PHNR.FO.61502649	ACTIVE	12/06/2023
PHNR.FO.61487308	ACTIVE	12/06/2023
PHWH.FX.61510291	ACTIVE	12/06/2023
DRCS.FX.61496320	ACTIVE	12/07/2023
DRSD.FX.61512569	ACTIVE	12/07/2023
DRSD.FX.61502635	ACTIVE	12/07/2023
PHNR.FO.61509171	ACTIVE	12/07/2023
PHWH.FX.61488380	ACTIVE	12/07/2023
PHWH.FX.61502629	ACTIVE	12/07/2023
PHWH.FX.61483253	ACTIVE	12/11/2023
PHWH.FX.61447674	ACTIVE	12/13/2023
PHWH.FX.61453249	ACTIVE	12/15/2023
PHHC.FX.61481285	ACTIVE	12/19/2023
DRCS.FX.61509519	ACTIVE	12/20/2023
DRSD.FX.61469494	ACTIVE	12/20/2023
DRSD.FX.61515830	ACTIVE	12/20/2023
PHNR.FO.61508311	ACTIVE	12/20/2023
PHNR.FO.61508585	ACTIVE	12/20/2023
PHWH.FX.61496698	ACTIVE	12/20/2023
PHWH.FX.61508298	ACTIVE	12/20/2023
PHWH.FX.61515840	ACTIVE	12/20/2023
PHHC.FX.61487961	ACTIVE	12/22/2023

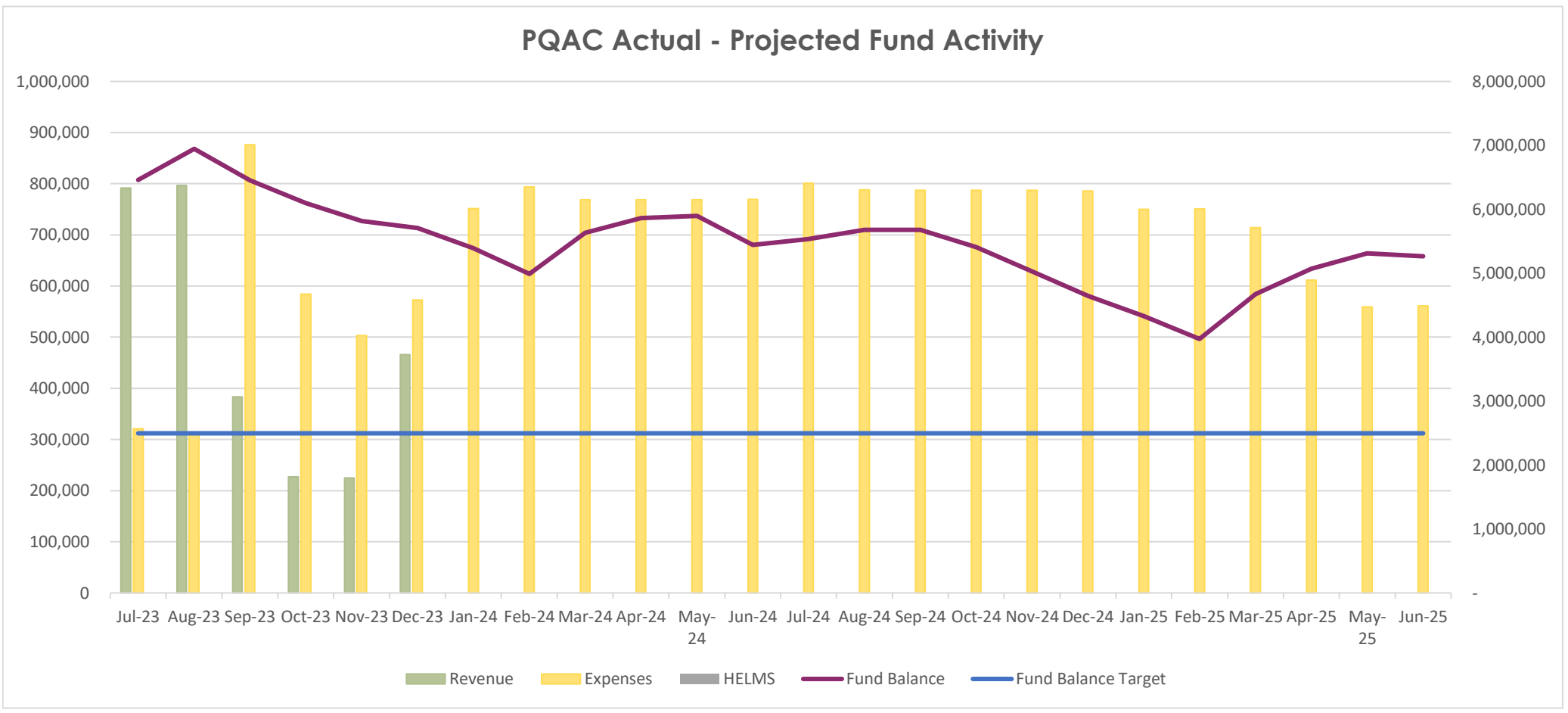
Credential #	Status	Expiration Date
PHNR.FO.61371300	CLOSED	12/02/2023
DRSD.FX.61436469	CLOSED	12/04/2023
PHAR.CF.60960888	CLOSED	12/04/2023
PHAR.CF.00004301	CLOSED	12/04/2023
PHAR.CF.00004351	CLOSED	12/04/2023
PHAR.CF.00059070	CLOSED	12/05/2023
PHWH.FX.60895097	CLOSED	12/05/2023
PHAR.CF.60099730	CLOSED	12/06/2023
PHAR.CF.00003705	CLOSED	12/06/2023
PHWH.FX.60821905	CLOSED	12/06/2023
PHNR.FO.61016607	CLOSED	12/08/2023
PHAR.CF.00003258	CLOSED	12/10/2023
DRCS.FX.00003828	CLOSED	12/13/2023
PHAR.CF.60003333	CLOSED	12/13/2023
PHWH.FX.60907364	CLOSED	12/13/2023
PHAR.CF.00000059	CLOSED	12/14/2023
PHAR.CF.00004295	CLOSED	12/14/2023
PHHC.FX.61163864	CLOSED	12/20/2023
PHNR.FO.61310389	CLOSED	12/20/2023
DRSD.FX.60438551	CLOSED	12/29/2023
PHMF.FX.60269968	CLOSED	12/29/2023
PHNR.FO.60798674	CLOSED	12/29/2023
PHWH.FX.60906113	CLOSED	12/29/2023
PHWH.FX.61403332	CLOSED	12/31/2023

Pharmacy Quality Assurance Commission
2023-25 Budget and Fund Balance Overview
For the period July 1, 2023 through December 31, 2023

Health Professions Account Beginning Fund Balance on July 1, 2023	**5,988,767**
Revenue To Date	2,889,043
23-25 HELMS Assessment To Date	194,727
Expenses To Date	3,971,718
Health Professions Account Fund Balance as of December 31, 2023	**4,711,365**

REVENUE	Est. Revenue	Actual Revenue	Variance	Variance %
To Date	3,523,997	2,889,043	(634,954)	82.0%
Biennium Total	16,979,058			17.02%

EXPENSES	Biennial Budget	Budget To Date	Expenses To Date	Variance To Date	Variance % To Date
Staff Salaries and Benefits	7,152,992	1,835,386	1,700,846	134,540	7.3%
Commission Pay	97,800	24,450	44,480	(20,030)	-81.9%
Professional Service Contracts	20,000	4,167	2,900	1,267	30.4%
Attorney General Support	545,064	136,266	97,091	39,175	28.7%
Goods and Services	62,736	15,684	8,666	7,018	44.7%
Travel	87,816	21,954	24,482	(2,528)	-11.5%
IT Equipment	20,936	10,468	10,263	205	2.0%
WA Recovery Asst. (WRAPP)	171,024	42,756	38,151	4,605	10.8%
Intra-Agency Charges - Discipline	1,670,330	479,259	345,419	133,840	27.9%
Intra-Agency Charges - Credentialing	3,194,376	876,765	773,404	103,361	11.8%
Intra-Agency Charges - Other	953,933	210,054	121,881	88,173	42.0%
TOTAL DIRECT COSTS	**13,977,007**	**3,657,209**	**3,167,583**	**489,626**	**13.4%**
Agency Indirect Costs	2,335,605	610,737	485,228	125,509	20.6%
Division Indirect Costs	1,560,076	407,962	318,906	89,056	21.8%
TOTAL INDIRECT COSTS	**3,895,682**	**1,018,699**	**804,135**	**214,565**	**21.1%**
TOTAL ALL COSTS	**17,872,689**	**4,675,908**	**3,971,718**	**704,190**	**15.1%**



Read this page carefully

WA Pharmacy Quality Assurance Commission
Pharmacy Self-Inspection Worksheet
2024 Long-Term Care Pharmacy Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

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

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

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

Date responsible pharmacy manager self-inspection was completed: Click or tap to enter a date.

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

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

Questions highlighted in **blue** are common areas of non-compliance observed during routine pharmacy inspections.

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

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

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

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
General Requirements							
☐	☐	☐	1		Do you fill medications for residents of a long-term care facility or hospice program?	**RCW 18.64.550** "(1) A chart order must be considered a prescription if it contains…"	Click or tap here to enter text.
☐	☐	☐	2		Does the pharmacy supply medications to long-term care facilities or hospice programs?		Click or tap here to enter text.
			3		Are medications filled from:		
☐	☐	☐	3	a	Prescriptions? See general inspection for prescription requirements.		Click or tap here to enter text.
☐	☐	☐	3	b	Chart orders? See question 4 or chart order requirements.		Click or tap here to enter text.
			4		Do the chart orders include: **Quantity is not required, and authorized signature may be the practitioner's agent, if order is for a non-controlled legend drug or over-the counter medication.**	**RCW 18.64.550(1)** A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature; (i) For written orders, the order must contain the	
☐	☐	☐	4	a	The full name of the patient		Click or tap here to enter text.

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

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

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

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

Read this Page Carefully

Pharmacy Quality Assurance Commission
2024 Manufacturer Self-Inspection Worksheet

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

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturer: Click or tap here to enter text.

Telephone: Click or tap here to enter text.

Fax: Click or tap here to enter text.

Address: Click or tap here to enter text.

DEA #: Click or tap here to enter text.

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

Endorsements: ☐ Controlled Substances

Document and Record Review

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

	Rule Reference
Manufacturer Self-Inspection Worksheet for last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Manufacturer License **Location:** Click or tap here to enter text.	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."
DEA Registration **Location:** Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."

	Rule Reference
Current Biennial Controlled Substance Inventory **Location:** Click or tap here to enter text.	**WAC 246-945-420**(2) "A facility shall conduct an inventory of controlled substances every two years." **21 CFR 1304.04(h)** "(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances **Location:** Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Schedule II Invoices for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(b)** "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." **21 CFR 1305.13(d)** "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the

	Rule Reference
	original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." **21 CFR 1305.13(e) "**The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 CFR 1305.22(g) "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106 and DEA Form 41) for the last 2 years **Location:** Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Quality and Control **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.22(d)** "The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed."
Sanitation **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 C.F.R 211.56** "(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed. (c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135)."
Cleaning and Maintenance **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 C.F.R 211.67(b)** "Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following: (1) Assignment of responsibility for cleaning and maintaining equipment; (2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; (3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance; (4) Removal or obliteration of previous batch identification; (5) Protection of clean equipment from contamination prior to use; (6) Inspection of equipment for cleanliness immediately before use."

	Rule Reference
Control of components and drug product containers and closures: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.80 (a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed."
Drug product containers and closures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.94(d)** "Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures."
Written procedures; deviations **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.100(a)** "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit."
Sampling and testing of in-process materials and drug products **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.110(a)** "To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate: (1) Tablet or capsule weight variation; (2) Disintegration time; (3) Adequacy of mixing to assure uniformity and homogeneity; (4) Dissolution time and rate; (5) Clarity, completeness, or pH of solutions. (6) Bioburden testing."
Control of microbiological contamination **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.113(a)** "Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed. (b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes."
Reprocessing **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.115(a)** "Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics."

	Rule Reference
Materials examination and usage criteria **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.122(a)** "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed."
Labeling issuance **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.125(f)** "Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed."
Packaging and labeling operations **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.130** "There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: (a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products. (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container. (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. (d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record. (e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records."
Warehousing procedures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.142** "Written procedures describing the warehousing of drug products shall be established and followed. They shall include: (a) Quarantine of drug products before release by the quality control unit. (b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected."
Distribution procedures **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.150** "Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary."

	Rule Reference
Laboratory control: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.160(b)(4)** "The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."
Testing and release for distribution **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.165(c)** "Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed."
Stability testing **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.166(a)** "There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include: (1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."
Special testing requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.167** "(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed. (b)For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed. (c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."
Records and reports: general requirements **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.180** "…(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for: (1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch. (2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under §211.192 for each drug product. (f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§211.198,

	Rule Reference
	211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration."
Master production and control records **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."
Complaint files **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.198(a)** "Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with §211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§310.305 and 514.80 of this chapter."
Returned drug products **Title:** Click or tap here to enter text. **Location:** Click or tap here to enter text.	**21 CFR 211.204** "…Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1.	Does the manufacturer have a current license?	**WAC 246-945-247(1)** "An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing."	Click or tap here to enter text.
☐	☐	☐	2.	Does the manufacturer have a current DEA registration?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Organization and Personnel – 21 CFR 211 Subpart B						
☐	☐	☐	3.	Does the organization have a quality control unit that is responsible for approving or rejecting drug products manufactured, processed, and packaged?	**21 CFR 211.22(a)** "There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company."	Click or tap here to enter text.
☐	☐	☐	4.	Does the quality control unit have adequate laboratory facilities?	**21 CFR 211.22(b)** "Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit."	Click or tap here to enter text.
☐	☐	☐	5.	Does the quality control unit approve or reject all procedures affecting the drug product identity, strength, quality, and purity?	**21 CFR 211.22(c)** "The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."	Click or tap here to enter text.
☐	☐	☐	6.	Are operations personnel appropriately trained?	**21 CFR 211.25(a)** "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them."	Click or tap here to enter text.
☐	☐	☐	7.	Are supervisory personnel appropriately trained?	**21 CFR 211.25(b)** "Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience,	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess."	
☐	☐	☐	8.	Is the facility adequately staffed for the operations performed?		**21 CFR 211.25(c)** "There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product."	Click or tap here to enter text.
☐	☐	☐	9.	Are personnel appropriately garbed?		**21 CFR 211.28(a)** "Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination."	Click or tap here to enter text.
☐	☐	☐	10.	Are personnel practicing good sanitation and health habits?		**21 CFR 211.28(b)** "Personnel shall practice good sanitation and health habits."	Click or tap here to enter text.
☐	☐	☐	11.	Do supervisors control access to operational areas?		**21 CFR 211.28(c)** "Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas."	Click or tap here to enter text.
☐	☐	☐	12.	Are personnel showing signs of illness or open wounds prohibited from contact with components or production operations?		**21 CFR 211.28(d)** "Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products."	Click or tap here to enter text.
			13.	Are records of consultants maintained to include the following:		**21 CFR 211.34** "Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide."	
☐	☐	☐	13.	a	Name of consultant		Click or tap here to enter text.
☐	☐	☐	13.	b	Address of consultant		Click or tap here to enter text.
☐	☐	☐	13.	c	Qualifications		Click or tap here to enter text.
☐	☐	☐	13.	d	Services provided		Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Buildings and Facilities - 21 CFR 211 Subpart C						
☐	☐	☐	14.	Is the facility appropriately constructed to accommodate cleaning, maintenance, and operations?	**21 C.F.R 211.42(a)** "Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations."	Click or tap here to enter text.
☐	☐	☐	15.	Do storage areas have adequate space for orderly placement of equipment and materials with flow through the building to prevent contamination?	**21 C.F.R 211.42(b)** "Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination."	Click or tap here to enter text.
☐	☐	☐	16.	Are there designated areas for each separate operation occurring within the facility?	**21 C.F.R 211.42(c)** "Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures: (1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging; (2) Holding rejected components, drug product containers, closures, and labeling before disposition; (3) Storage of released components, drug product containers, closures, and labeling; (4) Storage of in-process materials; (5) Manufacturing and processing operations; (6) Packaging and labeling operations; (7) Quarantine storage before release of drug products; (8) Storage of drug products after release; (9) Control and laboratory operations; (10) Aseptic processing…"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	17.	Are controlled substances stored separately in an appropriately secured area?	**WAC 246-945-565(4)** "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." **21 CFR 1301.72** "(a) Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas: (1) Where small quantities permit, a safe or steel cabinet; (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve. (2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or (3) A vault constructed after September 1, 1971: (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1⁄2 -inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings; (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry,	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open; (iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault; (v) The door of which vault is equipped with contact switches; and (vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration. (b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas: (1) A safe or steel cabinet as described in paragraph (a)(1) of this section; (2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section; (3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications: (i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section, (ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and: (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or; (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination; (4) A cage, located within a building on the premises, meeting the following specifications: (i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are: (a) At least one inch in diameter; (b) Set in concrete or installed with lag bolts that are pinned or brazed; and (c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches; (ii) Having a mesh construction with openings of not more than two and one-half inches across the square, (iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height, (iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and (v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage; (6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; (7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in §1301.71(b);…"	
☐	☐	☐	18.	Does the facility have adequately lighting?	**21 C.F.R 211.44** "Adequate lighting shall be provided in all areas."	Click or tap here to enter text.
☐	☐	☐	19.	Does the facility have proper ventilation, air filtration, and HVAC including temperature and humidity monitoring when appropriate? **Note: Refrigerators temperatures are to be maintained between 2- 8°C (36-46°F) and freezers between -25°& -10°C (-13° & 14°F)? ** Electronic monitoring is acceptable. **	**21 CFR 211.46** "(a) Adequate ventilation shall be provided. (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product. (c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants. (d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use."	Click or tap here to enter text.
☐	☐	☐	20.	Does the facility have positive pressure potable water with appropriate drainage?	**21 CFR 211.48** "(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR part 141. Water not meeting such standards shall not be permitted in the potable water system.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage."	
☐	☐	☐	21.	Is trash and refuse disposed of properly?	**21 CFR 211.50** "Sewage and refuse. Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner."	Click or tap here to enter text.
☐	☐	☐	22.	Is the facility maintained in a clean and sanitary condition?	**21 CFR 211.56(a)** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner."	Click or tap here to enter text.
☐	☐	☐	23.	Is the facility maintained in a good state of repair?	**21 CFR 211.58** "Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair."	Click or tap here to enter text.
Equipment - 21 CFR 211 Subpart D						
☐	☐	☐	24.	Is suitable equipment used during the manufacturing process?	**21 CFR 211.63** "Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance."	Click or tap here to enter text.
☐	☐	☐	25.	Is equipment appropriately constructed to prevent contamination of the products manufactured?	**21 CFR 211.65** "(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. (b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
			26.	Is equipment appropriately cleaned and maintained with documentation?		**21 CFR 211.67** "(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements… (c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§211.180 and 211.182."	
☐	☐	☐	26.	a	Assigned personnel		Click or tap here to enter text.
☐	☐	☐	26.	b	Maintenance and cleaning schedules		Click or tap here to enter text.
☐	☐	☐	26.	c	Description of maintenance and cleaning operations		Click or tap here to enter text.
☐	☐	☐	26.	d	Removal of previous batch identification		Click or tap here to enter text.
☐	☐	☐	26.	e	Equipment protected from contamination		Click or tap here to enter text.
☐	☐	☐	26.	f	Equipment inspections prior to use		Click or tap here to enter text.
☐	☐	☐	27.	Is equipment routinely calibrated per written procedures with appropriate records maintained?		**21 CFR 211.68(a)** "Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained."	Click or tap here to enter text.
☐	☐	☐	28.	Are appropriate controls in place to prevent changes to master production and control records?		**21 CFR 211.68(b)** "Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system..."	Click or tap here to enter text.
☐	☐	☐	29.	Is a backup file maintained for computerized systems?		**21 CFR 211.68(b)** "…A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained."	
☐	☐	☐	30.	Is the performance of equipment operations cross-checked by a second person?	**21 CFR 211.68(c)** "Such automated equipment used for performance of operations addressed by §§211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation."	Click or tap here to enter text.
☐	☐	☐	31.	Are non-fiber releasing filters used?	**21 CFR 211.72** "Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. The use of an asbestos-containing filter is prohibited."	Click or tap here to enter text.
Control of Components, Drug Product Containers and Closures – 21 C.F.R 211 Subpart E						
☐	☐	☐	32.	Are components, drug product containers, and closures stored appropriately to prevent contamination?	**21 CFR 211.80(b)** "Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination."	Click or tap here to enter text.
☐	☐	☐	33.	Are bagged or boxed drug product containers and closures stored off the floor with suitable spacing?	**21 CFR 211.80(c)** "Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	34.	Are containers for components or drug product containers or closures identified with a distinctive code and status?	**21 CFR 211.80(d)** "Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected)."	Click or tap here to enter text.
☐	☐	☐	35.	Are containers of components, drug product containers, and closures examined for damage, broken seals, and contamination upon receipt?	**21 CFR 211.82(a)** "Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination."	Click or tap here to enter text.
☐	☐	☐	36.	Are containers of components, drug product containers, and closures quarantined prior to approval for release?	**21 CFR 211.82(b)** "Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area shall conform to the requirements of §211.80."	Click or tap here to enter text.
☐	☐	☐	37.	Are containers of components, drug product containers, and closures sampled, tested, or examined and released for use by the quality control unit?	**21 CFR 211.84(a)** "Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit."	Click or tap here to enter text.
☐	☐	☐	38.	Are samples of each shipment of each lot retained for testing or examination in appropriate quantities?	**21 CFR 211.84(b)** "Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by §211.170."	Click or tap here to enter text.
☐	☐	☐	39.	Have samples been collected per procedure?	**21 CFR 211.84(c)** "Samples shall be collected in accordance with the following procedures: (1) The containers of components selected shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component. (2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					contents and contamination of other components, drug product containers, or closures. (3) Sterile equipment and aseptic sampling techniques shall be used when necessary. (4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing. 5) Sample containers shall be identified so that the following information can be determined: name of the material sampled, the lot number, the container from which the sample was taken, the date on which the sample was taken, and the name of the person who collected the sample. (6) Containers from which samples have been taken shall be marked to show that samples have been removed from them."	
☐	☐	☐	40.	Have samples been examined and tested as required?	**21 CFR 211.84(d)** "Samples shall be examined and tested as follows: (1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used. (2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. (3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(4) When appropriate, components shall be microscopically examined. (5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination. (6) Each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use."	
☐	☐	☐	41.	Are lots of components, drug product containers, or closures that do not meet specifications rejected?	**21 CFR 211.84(e)** "Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under paragraph (d) of this section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected."	Click or tap here to enter text.
☐	☐	☐	42.	Is stock appropriately rotated so that oldest approved stock is used first?	**21 CFR 211.86** "Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate."	Click or tap here to enter text.
☐	☐	☐	43.	Are lots of components, drug product containers, or closures retested or reexamined as appropriate for identity, strength, quality, and purity by the quality control unit for approval or rejection?	**21 CFR 211.87** "Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with §211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure."	Click or tap here to enter text.
☐	☐	☐	44.	Are rejected components, drug product containers, and closures identified and quarantined?	**21 CFR 211.89** "Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	Click or tap here to enter text.
☐	☐	☐	45.	Are drug product containers and closures reactive, additive, or absorptive?	**21 CFR 211.94(a)** "Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	46.	Do container closure systems provide adequate protection to prevent deterioration or contamination of the drug product?		**21 CFR 211.94(b)** "Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product."	Click or tap here to enter text.
☐	☐	☐	47.	Are drug product containers and closures clean and/or sterilized to assure they are suitable for their intended use?		**21 CFR 211.94(c)** "Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated."	Click or tap here to enter text.
Production and Process Controls – 21 CFR 211 Subpart F							
☐	☐	☐	48.	Is documentation of production and process controls recorded and justified including deviations from written procedures?		**21 CFR 211.100(b**) "Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."	Click or tap here to enter text.
☐	☐	☐	49.	Are batches formulated to provide 100 percent of the labeled or established amount of active ingredient?		**21 CFR 211.101(a)** "The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient."	Click or tap here to enter text.
			50.	Does repackaged component labeling include:		**21 CFR 211.101(b)** "Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information: (1) Component name or item code; (2) Receiving or control number; (3) Weight or measure in new container; (4) Batch for which component was dispensed, including its product name, strength, and lot number."	
☐	☐	☐	50.	1	Component name or item code;		Click or tap here to enter text.
☐	☐	☐	50.	2	Receiving or control number;		Click or tap here to enter text.
☐	☐	☐	50.	3	Weight or measure in new container;		Click or tap here to enter text.
☐	☐	☐	50.	4	Batch for which component was dispensed, including its product name, strength, and lot number?		Click or tap here to enter text.
			51.	Is each container of component dispensed to manufacturing verified by a second person to assure:		**21 CFR 211.101(c)** "Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: (1) The component was released by the quality control unit;	
☐	☐	☐	51.	1	The component was released by the quality control unit;		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	51.	2	The weight or measure is correct as stated in the batch production records;	(2) The weight or measure is correct as stated in the batch production records; (3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under §211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section."	Click or tap here to enter text.
☐	☐	☐	51.	3	The containers are properly identified?		Click or tap here to enter text.
☐	☐	☐	52.		Is each component either added to the batch by one person and verified by a second person or, if the components are added by automated equipment, only verified by one person?	**21 CFR 211.211(d)** "Each component shall either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment under §211.68, only verified by one person."	Click or tap here to enter text.
☐	☐	☐	53.		Are actual yields and percentages of theoretical yield determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product?	**21 CFR 211.103** "Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product…"	Click or tap here to enter text.
☐	☐	☐	54.		Are yield calculations performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person?	**21 CFR 211.103** "…Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under §211.68, be independently verified by one person."	Click or tap here to enter text.
☐	☐	☐	55.		Are all storage containers, processing lines, and major equipment used during batch production properly identified at all times?	**21 CFR 211.105(a)** "All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch."	Click or tap here to enter text.
☐	☐	☐	56.		Is identification of major equipment included in batch production records?	**21 CFR 211.105(b)** "Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	57.	Are in-process specifications consistent with or within acceptable variability estimates for drug product final specifications?	**21 CFR 211.110(b)** "Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications."	Click or tap here to enter text.
☐	☐	☐	58.	Are in-process materials tested for identity, strength, quality, and purity, and approved or rejected by the quality control unit?	**21 CFR 211.110(c)** "In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods."	Click or tap here to enter text.
☐	☐	☐	59.	Are rejected in-process materials identified and quarantined to prevent use?	**21 CFR 211.110(d)** "Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable."	Click or tap here to enter text.
☐	☐	☐	60.	Are time limits for completion of each phase of production established with any deviations justified and documented?	**21 CFR 211.111** "When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented."	Click or tap here to enter text.
☐	☐	☐	61.	Is reprocessing performed only after review and approval of the quality control unit?	**21 CFR 211.115(b)** "Reprocessing shall not be performed without the review and approval of the quality control unit."	Click or tap here to enter text.
Packaging and Labeling Control – 21 CFR 211 Subpart G						
☐	☐	☐	62.	Are labeling and packaging materials representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product?	**21 CFR 211.122(a)** "…Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product."	Click or tap here to enter text.
☐	☐	☐	63.	Are labeling or packaging materials approved and released for use meeting appropriate written specifications?	**21 CFR 211.122(b)** "Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					rejected to prevent their use in operations for which they are unsuitable."	
☐	☐	☐	64.	Are records maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected?	**21 CFR 211.122(c)** "Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected."	Click or tap here to enter text.
☐	☐	☐	65.	Are labels and labeling materials for different drug products stored separately with suitable identification and access to the storage area limited to authorized personnel?	**21 CFR 211.122(d)** "Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel."	Click or tap here to enter text.
☐	☐	☐	66.	Are obsolete and outdated labels, labeling, and other packaging materials destroyed?	**21 CFR 211.122(e)** "Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed."	Click or tap here to enter text.
☐	☐	☐	67.	Is use of gang-printed labeling prohibited unless differentiated by size, shape, or color?	**21 CFR 211.122(f)** "Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color."	Click or tap here to enter text.
☐	☐	☐	68.	Does cut labeling include at least one special control procedure?	**21 CFR 211.122(g)** "If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures: (1) Dedication of labeling and packaging lines to each different strength of each different drug product; (2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or (3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment."	
☐	☐	☐	69.	Are printing devices monitored to assure that all imprinting conforms to the print specified in the batch production record?	**21 CFR 211.122(h)** "Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record."	Click or tap here to enter text.
☐	☐	☐	70.	Is strict control exercised in drug product labeling operations?	**21 CFR 211.125(a)** "Strict control shall be exercised over labeling issued for use in drug product labeling operations."	Click or tap here to enter text.
☐	☐	☐	71.	Are labeling materials examined to the specifications in the master or batch production records?	**21 CFR 211.125(b)** "Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records."	Click or tap here to enter text.
☐	☐	☐	72.	Is there a reconciliation process to evaluate labeling quantity discrepancies?	**21 CFR 211.125(c)** "Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with §211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with §211.122(g)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers."	Click or tap here to enter text.
☐	☐	☐	73.	Are excess labeling bearing lot or control numbers destroyed?	**21 CFR 211.125(d)** "All excess labeling bearing lot or control numbers shall be destroyed."	Click or tap here to enter text.
☐	☐	☐	74.	Are returned labeling maintained and stored in a manner to prevent mix-ups and provide proper identification?	**21 CFR 211.125(e)** "Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification."	Click or tap here to enter text.
☐	☐	☐	75.	Are OTC drug products packaged for retail sales in tamper-evident packaging?	**21 CFR 211.132(b)(1)** "Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or lozenge product) for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale. A	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					tamper-evident package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display."	
☐	☐	☐	76.	Are two-piece, hard gelatin capsules for OTC retail sale sealed using tamper-evident technology?	**21 CFR 211.132(b)(2)** "In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology."	Click or tap here to enter text.
☐	☐	☐	77.	Does OTC drug packaging contain a statement identifying all tamper-evident features?	**21 CFR 211.132(c)** "(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that: (i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with paragraph (b) of this section; (ii) Is prominently placed on the package; and (iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck.""	
☐	☐	☐	78.	Is the FDA notified of changes in packaging and labeling for OTC drug products subject to new drug applications?	**21 CFR 211.132(e)** "OTC drug products subject to approved new drug applications. Holders of approved new drug applications for OTC drug products are required under §314.70 of this chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this section. Changes in packaging and labeling required by this regulation may be made before FDA approval, as provided under §314.70(c) of this chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under §314.70(b) of this chapter."	Click or tap here to enter text.
☐	☐	☐	79.	Are packaged and labeled products sampled and examined to confirm containers and packages have the correct label with the results documented?	**21 CFR 211.134** "(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label. (b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling. (c) Results of these examinations shall be recorded in the batch production or control records."	Click or tap here to enter text.
☐	☐	☐	80.	Does drug product labeling bear an appropriate expiration date, unless exempt?	**21 CFR 211.137** "(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166. (b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in §211.166. (c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(d) Expiration dates shall appear on labeling in accordance with the requirements of §201.17 of this chapter. (e) Homeopathic drug products shall be exempt from the requirements of this section. (f) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section. (g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product. (h) Pending consideration of a proposed exemption, published in the Federal Register of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data."	
Laboratory Controls - 21 CFR 211 Subpart I						
☐	☐	☐	81.	Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any changes, reviewed and approved by the quality control unit?	**21 CFR 211.160(a)** "The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit."	Click or tap here to enter text.
☐	☐	☐	82.	Are specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms followed and documented including justification for any deviations?	**21 CFR 211.160(a)** "…The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified."	Click or tap here to enter text.
			83.	Do laboratory controls include the following:	**21 CFR 211.160(b)** "Laboratory controls shall include the establishment of scientifically sound and appropriate	

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	83.	1	Conformity to specifications for the acceptance of each lot of components, containers, closures, and labeling	specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: (1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration. (2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified. (3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified. (4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used."	Click or tap here to enter text.
☐	☐	☐	83.	2	Conformity to specifications for sampling and testing procedures for in-process materials.		Click or tap here to enter text.
☐	☐	☐	83.	3	Conformity to sampling procedures and specifications for drug products		Click or tap here to enter text.
☐	☐	☐	83.	4	Calibration of instruments, apparatus, gauges, and recording devices at suitable intervals?		Click or tap here to enter text.
☐	☐	☐	84.		Is each batch of drug products tested for conformance to final specifications for identify and strength of active ingredients prior to release?	**21 CFR 211.165(a)** "For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible."	
☐	☐	☐	85.	Is each batch of drug product tested to be free of objectionable microorganisms?	**21 CFR 211.165(b)** "There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms."	Click or tap here to enter text.
☐	☐	☐	86.	Is acceptance criteria for sampling and testing, including acceptance and rejection levels, adequate to assure batches of drug products meet all specifications and quality control criteria?	**21 CFR 211.165(d)** "Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels."	Click or tap here to enter text.
☐	☐	☐	87.	Are test methods established and documented for accuracy, sensitivity, specificity, and reproducibility?	**21 CFR 211.165(e)** "The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with §211.194(a)(2)."	Click or tap here to enter text.
☐	☐	☐	88.	Are drug products failing to meet established standards or specifications rejected?	**21 CFR 211.165(f)** "Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria."	Click or tap here to enter text.
☐	☐	☐	89.	Are batches of each drug product tested to determine an appropriate expiration date with records maintained?	**21 CFR 211.166(b)** "An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	90.	Are homeopathic drug products assessed for stability and compatibility to ensure there is no degradation of product for the expected period of use?	**21 CFR 211.166(c)** "For homeopathic drug products, the requirements of this section are as follows: (1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use. (2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed."	Click or tap here to enter text.
☐	☐	☐	91.	Are drug products purporting to be sterile and/or pyrogen-free tested to determine conformance to such requirements?	**21 CFR 211.167(a)** "For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	92.	Are ophthalmic ointments tested for the presence of foreign particles and harsh or abrasive substances?	**21 CFR 211.167(b)** "For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	93.	Are controlled-release dosage forms tested for conformance to rate of release specifications for each active ingredient?	**21 CFR 211.167(c)** "For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	94.	Are reserve samples of drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(1)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					expiration date of the last lot of the drug product containing the active ingredient."	
☐	☐	☐	95.	Are reserve samples of radioactive drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(2)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for: (i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days."	Click or tap here to enter text.
☐	☐	☐	96.	Are reserve samples of OTC drug products retained in appropriate quantities for the required time frame?	**21 CFR 211.170(a)(3)** "An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows: For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under §211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient."	Click or tap here to enter text.
☐	☐	☐	97.	Are reserve samples of each lot or batch of drug products stored consistent with product labeling and visually examined at least yearly with results documented?	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample	Click or tap here to enter text.

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

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for: (i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or (ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days…"	
☐	☐	☐	99.	Are reserve samples of each lot or batch of OTC drug products stored consistent with product labeling and visually examined at least yearly with results documented?	**21 CFR 211.170(b)** "An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with §211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows: … (3) For an OTC drug product that is exempt for bearing an expiration date under §211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed."	Click or tap here to enter text.
☐	☐	☐	100.	Are animals used in testing maintained in a suitable manner with appropriate records of their use?	**21 CFR 211.173** "Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	101.	Are non-penicillin containing drug products exposed to cross-contamination with penicillin tested for the presence of penicillin?	**21 CFR 211.176** "If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference."	Click or tap here to enter text.
Records and Reports – 21 CFR 211 Subpart J						
☐	☐	☐	102.	Are production, control, and distribution records of drug products, components, containers, closures, and labeling retained for 1 year after the expiration date, or 3 years after distribution for OTC drug products lacking expiration dating? **Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.	**21 CFR 211.180** "(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the batch. (b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under §211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling."	Click or tap here to enter text.
☐	☐	☐	103.	Are production, control, and distribution records readily available during the retention period at the place where the activities occurred? **Note: Pharmaceutical firm recordkeeping WAC 246-945-020 requires all records to be kept for a minimum of 2 years in a readily retrievable form and location.	**21 CFR 211.180(c)** "All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph."	Click or tap here to enter text.
☐	☐	☐	104.	Are written records maintained so data can be used to annually evaluate the quality standards of each drug product?	**21 CFR 211.180(e)** "Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures…"	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	105.		Do signed and dated equipment cleaning and maintenance logs include the date, time, product, and lot number of each batch processed in chronological order?	**21 CFR 211.182** "A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under §211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order."	Click or tap here to enter text.
			106.		Do component, container, closure, and labeling records include:	**21 CFR 211.184** Component, drug product container, closure, and labeling records shall include "(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in §211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known. (b) The results of any test or examination performed (including those performed as required by §211.82(a), §211.84(d), or §211.122(a)) and the conclusions derived therefrom. (c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product	
☐	☐	☐	106.	a	The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s); the receiving code; and the date of receipt		Click or tap here to enter text.
☐	☐	☐	106.	b	The results of any test or examination performed		Click or tap here to enter text.
☐	☐	☐	106.	c	An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	106.	d	Documentation of the examination and review of labels and labeling	associated with the use of each component, drug product container, and closure. (d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§211.122(c) and 211.130(c). (e) The disposition of rejected components, drug product containers, closure, and labeling."	Click or tap here to enter text.
☐	☐	☐	106.	e	The disposition of rejected components, drug product containers, closure, and labeling?		Click or tap here to enter text.
☐	☐	☐	107.		Do master production and control records for each batch include the batch size, date, and signatures?	**21 CFR 211.186(a)** "To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed."	Click or tap here to enter text.
			108.		Do master production and control records include:	**21 CFR 211.186(b)** "Master production and control records shall include: (1) The name and strength of the product and a description of the dosage form; (2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit; (3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic; (4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records; (5) A statement concerning any calculated excess of component;	
☐	☐	☐	108.	1	Name, strength, and dosage form of the product		Click or tap here to enter text.
☐	☐	☐	108.	2	Name and weight or measure of each active ingredient		Click or tap here to enter text.
☐	☐	☐	108.	3	List of components designated by name or code indicating any special quality characteristic		Click or tap here to enter text.
☐	☐	☐	108.	4	Weight or measure of each component		Click or tap here to enter text.
☐	☐	☐	108.	5	Statement of any calculated excess of component		Click or tap here to enter text.
☐	☐	☐	108.	6	Statement of theoretical weight at appropriate phases of processing		Click or tap here to enter text.
☐	☐	☐	108.	7	Statement of maximum and minimum theoretical yield expected		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	108.	8	Description of containers, closures, packaging materials, copy of the label, and all other labeling	(6) A statement of theoretical weight or measure at appropriate phases of processing; (7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to §211.192 is required; (8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling; (9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed."	Click or tap here to enter text.
☐	☐	☐	108.	9	Complete manufacturing and control instructions, sampling and testing procedures, and specifications?		Click or tap here to enter text.
☐	☐	☐	109.		Do batch production and control records include a copy of the signed and dated master production record?	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: (a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;…"	Click or tap here to enter text.
☐	☐	☐	110.		Do batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished?	**21 CFR 211.188** "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: … (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: (1) Dates; (2) Identity of individual major equipment and lines used; (3) Specific identification of each batch of component or in-process material used; (4) Weights and measures of components used in the course of processing; (5) In-process and laboratory control results; (6) Inspection of the packaging and labeling area before and after use; (7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(8) Complete labeling control records, including specimens or copies of all labeling used; (9) Description of drug product containers and closures; (10) Any sampling performed; (11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under §211.68, the identification of the person checking the significant step performed by the automated equipment. (12) Any investigation made according to §211.192. (13) Results of examinations made in accordance with §211.134."	
☐	☐	☐	111.	Are drug product production and control records, including packaging and labeling records, reviewed and approved by the quality control unit?	**21 CFR 211.192** "All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup."	Click or tap here to enter text.
☐	☐	☐	112.	Do laboratory records include complete data derived from all tests necessary to assure compliance with specifications and standards?	**21 CFR 211.194(a)** "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows: (1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.	Click or tap here to enter text.

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

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

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with §211.180(c). (3) Where an investigation under §211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination."	
Returned and Salvaged Drug Products – 21 CFR 211 Subpart K						
☐	☐	☐	119.	Are returned drug products examined, tested, or investigated prior to reprocessing, if applicable, with results documented?	**21 CFR 211.204** "Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of §211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed."	Click or tap here to enter text.
☐	☐	☐	120.	Are drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke,	**21 CFR 211.208** "Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or	Click or tap here to enter text.

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

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	124.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 C.F.R 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	125.	Is an inventory of controlled substances being performed every 2 years? ** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances. **	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)** "(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	Click or tap here to enter text.
☐	☐	☐	126.	Does the manufacturer have power of attorney forms for ordering schedule II controlled substances?	**21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	127.	Has the manufacturer reported a loss of controlled substances in the previous 24 months to the DEA and the Pharmacy Quality Assurance Commission?	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-9945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.
Additional Federal and Washington State Specific Regulations						
☐	☐	☐	128.	Are solid dosage form legend drugs, labeling and packaging, clearly marked or imprinted as required?	**21 CFR 206.10(a)** "Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature." **RCW 69.41.200** "(1) No legend drug in solid dosage form may be manufactured or commercially distributed within this state unless it has clearly marked or imprinted on it an individual symbol, number, company name, words, letters, marking, or National Drug Code number identifying the drug and the manufacturer or distributor of such drug. (2) No manufacturer or distributor may sell any legend drug contained within a bottle, vial, carton, or other container, or in any way affixed or appended to or enclosed within a package of any kind designed or intended for delivery in such container or package to an ultimate consumer within this state unless such container or package has clearly and	Click or tap here to enter text.

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

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

WA Pharmacy Quality Assurance Commission

2024 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 and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

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

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

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: Click or tap here to enter text.

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

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

WAC 246-945-100(1)(c) "All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration: (c) USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings"

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

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
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 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.	Click or tap here to enter text.
☐	☐	☐	13.	Do areas where HDs are handled have a hazard sign displayed before the entrance?			Click or tap here to enter text.
☐	☐	☐	14.	Does the HD handling area have restricted access?			Click or tap here to enter text.
☐	☐	☐	15.	Are HD handling areas located away from breakrooms and refreshment areas for personnel, patients, or visitors?			Click or tap here to enter text.
			16.	Does the facility have areas designated for:			
☐	☐	☐	16.	a	Receipt and unpacking		Click or tap here to enter text.
☐	☐	☐	16.	b	Storage of HDs		Click or tap here to enter text.
☐	☐	☐	16.	c	Nonsterile HD compounding (if performed by the entity)		Click or tap here to enter text.
☐	☐	☐	16.	d	Sterile HD compounding (if performed by the entity)		Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	18.	Does the facility ensure that HDs are not unpacked in sterile compounding areas or in positive pressure areas?			Click or tap here to enter text.
☐	☐	☐	19.	Are HDs stored in a manner to prevent spills or breaks?		**USP Chapter 800- 5.2 STORAGE**	Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	20.		Are all antineoplastic HDs requiring manipulation, other than counting or repackaging of final dosage forms, and any HD APIs stored separately from non-HDs?	HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips. 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.	Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	22.		Are refrigerated antineoplastic HDs stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH?		Click or tap here to enter text.
☐	☐	☐	23.		Does sterile or nonsterile compounding of HDs occur in a C-PEC located in a C-SEC?	**USP Chapter 800- 5.3 COMPOUNDING** Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile and nonsterile compounding must: be externally vented; be physically separated (i.e., a different room from other preparation areas); have an appropriate air exchange (e.g., ACPH); have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas. The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding. If there is any loss of power to	Click or tap here to enter text.
			24.		Does the C-SEC used for sterile and nonsterile compounding include:		
☐	☐	☐	24.	a	External ventilation		Click or tap here to enter text.
☐	☐	☐	24.	b	Physical separation		Click or tap here to enter text.
☐	☐	☐	24.	c	Appropriate air exchange		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	24.	d	Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas	the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately per the manufacturer's recommendations. Once the C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and 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.	Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	26.		Is the C-PEC decontaminated, cleaned, and disinfected prior to use if not operated continuously?		Click or tap here to enter text.
☐	☐	☐	27.		Is a sink available for handwashing?		Click or tap here to enter text.
☐	☐	☐	28.		Are eyewash stations and/or other emergency or safety precautions readily available?		Click or tap here to enter text.
☐	☐	☐	29.		Are water sources and drains located to prevent interference with required ISO classifications?		Click or tap here to enter text.
☐	☐	☐	30.		Are water sources and drains at least 1 meter from the C-PEC?		Click or tap here to enter text.
☐	☐	☐	31.		If compounding nonsterile and sterile HDs in the same room, is the nonsterile C-PEC sufficiently effective to allow the room to maintain ISO 7 classification throughout the nonsterile compounding activity?		Click or tap here to enter text.
☐	☐	☐	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		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				occurring when sterile compounding is in process?		
☐	☐	☐	33.	Does the facility follow USP <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 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.	Click or tap here to enter text.
☐	☐	☐	34.	Do C-PECs used for manipulation of nonsterile HDs have either external ventilation or redundant–HEPA filters in series?		Click or tap here to enter text.
☐	☐	☐	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.****		Click or tap here to enter text.
☐	☐	☐	36.	Is the C-PEC placed in a C-SEC that has at least 12 ACPH?		Click or tap here to enter text.
☐	☐	☐	37.	Are surfaces in the nonsterile compounding area smooth, impervious, free from cracks and crevices, and non-shedding?		Click or tap here to enter text.
☐	☐	☐	38.	Does the facility follow USP <797> for sterile compounding?	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING** In addition to this chapter, sterile compounding must	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	39.	Are all C-PECs used for manipulation of sterile HDs externally vented?	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.	Click or tap here to enter text.
☐	☐	☐	40.	Do C-PECs maintain ISO Class 5 or better air quality?		Click or tap here to enter text.
☐	☐	☐	41.	Are LAFWs or CAIs prohibited from use for compounding of antineoplastic HDs?		Click or tap here to enter text.
☐	☐	☐	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 used for HDs?		Click or tap here to enter text.
☐	☐	☐	43.	Is the C-PEC located in a C-SEC?		Click or tap here to enter text.
☐	☐	☐	44.	Do BUDs of products compounded in a C-SCA follow <797>?		Click or tap here to enter text.
			45.	If the negative-pressure buffer room is entered through the positive-pressure non-HD buffer room, are the following requirements met:	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING: ISO CLASS 7 BUFFER ROOM WITH AN ISO CLASS 7 ANTE-ROOM** The C-PEC is placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH. The buffer room must be externally vented. Because the room through which entry into the HD buffer room (e.g., ante-	
☐	☐	☐	45.	a A line of demarcation is defined in the negative pressure buffer room for donning and doffing PPE		Click or tap here to enter text.

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

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

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	49.	Are only low- and medium-risk HD CSPs prepared in the C-SCA?		Click or tap here to enter text.
☐	☐	☐	50.	Do HD CSPs comply with the BUDs in <797> for CSPs prepared in a SCA?		Click or tap here to enter text.
☐	☐	☐	51.	Are CSTDs used when administering antineoplastics?	**USP Chapter 800- 5.4 CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS** CSTDs must be used when administering antineoplastic HDs when the dosage form allows. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.	Click or tap here to enter text.
Personal Protective Equipment						
☐	☐	☐	52.	Is disposable PPE discarded after a single use?	**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.	Click or tap here to enter text.
☐	☐	☐	53.	Is reusable PPE decontaminated and cleaned after use?		Click or tap here to enter text.
☐	☐	☐	54.	Is appropriate PPE worn during handling of HDs when receiving, storing, transporting, compounding, cleaning and disinfecting, administering, spill control, and waste disposal?	**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Two pairs of chemotherapy gloves are required for administering injectable antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs. For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see Types of Exposure) and activities performed. Appropriate PPE must be worn when handling HDs including during: receipt; storage; transport; compounding (sterile and nonsterile); administration deactivation/decontamination, cleaning, and disinfecting; spill control; waste disposal.	Click or tap here to enter text.
			55.	If chemotherapy gloves are used, do they meet the following:	**USP Chapter 800- 7.1 GLOVES**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	55.	a	ASTM standard D6978	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 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.	Click or tap here to enter text.
☐	☐	☐	55.	b	Powder-free		Click or tap here to enter text.
☐	☐	☐	55.	c	Inspected for defects before use		Click or tap here to enter text.
☐	☐	☐	55.	d	Sterile outer gloves used when sterile compounding		Click or tap here to enter text.
☐	☐	☐	55.	e	Change outer gloves every 30 minutes unless otherwise recommended by the manufacturer's documentation		Click or tap here to enter text.
☐	☐	☐	55.	f	Changed when torn, punctured, or contaminated		Click or tap here to enter text.
☐	☐	☐	56.	Are hands washed with soap and water after removing gloves?			Click or tap here to enter text.
			57.	Do gowns meet the following requirements:		**USP Chapter 800- 7.2 GOWNS** When gowns are required, they must be disposable and shown to resist permeability by HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact and may transfer to other healthcare workers or various surfaces. Washing of non-disposable clothing contaminated with HD residue should	
☐	☐	☐	57.	a	Disposable		Click or tap here to enter text.
☐	☐	☐	57.	b	Resist permeability by HDs		Click or tap here to enter text.
☐	☐	☐	57.	c	Close in the back		Click or tap here to enter text.
☐	☐	☐	57.	d	Long sleeved		Click or tap here to enter text.
☐	☐	☐	57.	e	Closed cuffs that are elastic or knit		Click or tap here to enter text.
☐	☐	☐	57.	f	Does not have seams or closures that could allow HDs to pass through		Click or tap here to enter text.
☐	☐	☐	58.	Is potentially contaminated clothing not taken home under any circumstances?			Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	59.	Are gowns changed per the manufacturer's information for permeation of the gown? ****If no permeation information is available for the gowns used, changing them every 2–3 hours or immediately after a spill or splash is acceptable.****	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.	Click or tap here to enter text.
☐	☐	☐	60.	Are gowns only worn in the HD handling areas?		Click or tap here to enter text.
☐	☐	☐	61.	Is a second pair of shoe covers donned prior to entering the C-SEC and doffed upon exiting the C-SEC?	**USP Chapter 800- 7.3 HEAD, HAIR, SHOE, AND SLEEVE COVERS** When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.	Click or tap here to enter text.
☐	☐	☐	62.	Is eye and face protection worn when there is a risk of a spill or splash?	**USP Chapter 800- 7.4 EYE AND FACE PROTECTION** Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). A full-face piece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.	Click or tap here to enter text.
☐	☐	☐	63.	If required, is appropriate respiratory protection provided and used?	**USP Chapter 800- 7.5 RESPIRATORY PROTECTION** Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required.	Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	64.		Is PPE placed into an appropriate waste container and disposed of per local, state, and federal regulations?	**USP Chapter 800- 7.6 DISPOSAL OF USED PERSONAL PROTECTIVE EQUIPMENT** Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. 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.	Click or tap here to enter text.
☐	☐	☐	65.		Are outer 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.****		Click or tap here to enter text.
Hazard Communication Program							
☐	☐	☐	66.		Does the entity have established policies and procedures that ensure worker safety during HD handling?	**USP Chapter 800- 8 HAZARD COMMUNICATION PROGRAM** Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Elements of the hazard communication program plan must include: a written plan that describes how the standard will be implemented; all containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings; entities must have an SDS for each hazardous chemical they use (29 CFR 1910.1200); entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas; personnel who may be	Click or tap here to enter text.
			67.		Does the entity have HD SOPs for the following:		
☐	☐	☐	67.	a	Labeling		Click or tap here to enter text.
☐	☐	☐	67.	b	Transport		Click or tap here to enter text.
☐	☐	☐	67.	c	Storage		Click or tap here to enter text.
☐	☐	☐	67.	d	Disposal		Click or tap here to enter text.
☐	☐	☐	67.	e	Use of Safety Data Sheets (SDS)		Click or tap here to enter text.
			68.		Does the hazard communication program plan include the following:		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	68.	a	A written plan describing how the standard will be implemented	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.	Click or tap here to enter text.
☐	☐	☐	68.	b	Labeling, tagging, or marking of hazardous chemical containers that identify the material and include appropriate hazard warnings		Click or tap here to enter text.
☐	☐	☐	68.	c	SDSs for each hazardous chemical used are readily available to personnel		Click or tap here to enter text.
☐	☐	☐	68.	d	Information and training for personnel before initial assignment to work with a hazardous chemical and whenever the hazard changes		Click or tap here to enter text.
☐	☐	☐	68.	e	Written confirmation from personnel of reproductive capability understanding the risks of handling HDs		Click or tap here to enter text.
Personnel Training							
☐	☐	☐	69.		Are all personnel who handle HDs trained for their job functions?	**USP Chapter 800- 9 PERSONNEL TRAINING** All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change	Click or tap here to enter text.
☐	☐	☐	70.		Does training occur before the employee independently handles HDs?		Click or tap here to enter text.
☐	☐	☐	71.		Is effectiveness of training demonstrated by each employee?		Click or tap here to enter text.
☐	☐	☐	72.		Is personnel competency reassessed at least every 12 months?		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			73.	Are personnel trained prior to the following:		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.	
☐	☐	☐	73.	a	Introduction of a new HD		Click or tap here to enter text.
☐	☐	☐	73.	b	Introduction of new equipment		Click or tap here to enter text.
☐	☐	☐	73.	c	New or significant change in process or SOP		Click or tap here to enter text.
☐	☐	☐	74.	Are all training and competency assessments documented?			Click or tap here to enter text.
			75.	Does the training include the following:			
☐	☐	☐	75.	a	Overview of entity's list of HDs and their risks		Click or tap here to enter text.
☐	☐	☐	75.	b	Review of the entity's SOPs related to handling of HDs		Click or tap here to enter text.
☐	☐	☐	75.	c	Proper use of PPE		Click or tap here to enter text.
☐	☐	☐	75.	d	Proper use of equipment and devices		Click or tap here to enter text.
☐	☐	☐	75.	e	Response to known or suspected HD exposure		Click or tap here to enter text.
☐	☐	☐	75.	f	Spill management		Click or tap here to enter text.
☐	☐	☐	75.	g	Proper disposal of HDs and trace-contaminated materials		Click or tap here to enter text.
Receiving							
☐	☐	☐	76.	Does the entity establish SOPs for receiving HDs?		**USP Chapter 800- 10 RECEIVING** The entity must establish SOPs for receiving HDs. HDs must be delivered to the HD storage area immediately after unpacking. PPE, including chemotherapy gloves, must be worn when unpacking HDs (see Personal	Click or tap here to enter text.
☐	☐	☐	77.	Are HDs delivered to the HD storage area immediately after unpacking?			Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	78.	Is PPE worn when unpacking HDs?		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 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.	Click or tap here to enter text.
☐	☐	☐	79.	Is a spill kit accessible in the receiving area?			Click or tap here to enter text.
☐	☐	☐	80.	Does the entity enforce policies regarding HD receiving?			Click or tap here to enter text.
☐	☐	☐	81.	If a sterile compounding C-PEC is used when opening damaged shipping containers, is it disinfected after decontamination, deactivation, and cleaning before returning to sterile compounding activity?			Click or tap here to enter text.
			82.	Are damaged packages or shipping cartons:			
☐	☐	☐	82.	a	Considered spills		Click or tap here to enter text.
☐	☐	☐	82.	b	Reported to the designated person		Click or tap here to enter text.
☐	☐	☐	82.	c	Managed according to the entity's SOPs		Click or tap here to enter text.
☐	☐	☐	83.	Does clean-up comply with established SOPs?			Click or tap here to enter text.
Labeling, Packaging, Transport and Disposal							
			84.	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.	
☐	☐	☐	84.	a	Labeling		Click or tap here to enter text.
☐	☐	☐	84.	b	Packaging		Click or tap here to enter text.
☐	☐	☐	84.	c	Transporting		Click or tap here to enter text.
☐	☐	☐	84.	d	Disposal		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	85.	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.	Click or tap here to enter text.
☐	☐	☐	86.	Do labeling processes prevent introduction of contamination in non-HD handling areas?		Click or tap here to enter text.
☐	☐	☐	87.	Does packaging maintain physical integrity, stability, and sterility during transport?	**USP Chapter 800- 11.2 PACKAGING** Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.	Click or tap here to enter text.
☐	☐	☐	88.	Does packaging protect the HD product from damage, leakage, contamination, and degradation during transport?		Click or tap here to enter text.
☐	☐	☐	89.	Are there written SOPs for appropriate shipping containers and insulating materials?		Click or tap here to enter text.
☐	☐	☐	90.	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.	Click or tap here to enter text.
☐	☐	☐	91.	Are HDs transported in containers that minimize the risk of breakage or leakage?		Click or tap here to enter text.
☐	☐	☐	92.	Does the entity not use pneumatic tubes to transport liquid or antineoplastic HDs?		Click or tap here to enter text.
☐	☐	☐	93.	Does the entity consult the SDS when shipping HDs?		Click or tap here to enter text.
☐	☐	☐	94.	Does the entity's HD labeling include storage, disposal, and HD category information consistent with the carrier's policies?		Click or tap here to enter text.
☐	☐	☐	95.	Are personnel trained to properly dispose of HDs?	**USP Chapter 800- 11.4 DISPOSAL**	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	96.	Does HD disposal comply with all applicable regulations?	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.	Click or tap here to enter text.
Dispensing Final Dosage Forms						
☐	☐	☐	97.	Is counting or repackaging of HDs done carefully?	**USP Chapter 800- 12. DISPENSING FINAL DOSAGE FORMS** 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.	Click or tap here to enter text.
☐	☐	☐	98.	Does the facility prohibit placement of antineoplastic HDs in counting or packaging machines?		Click or tap here to enter text.
Compounding						
☐	☐	☐	99.	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	Click or tap here to enter text.
☐	☐	☐	100.	Is compounding performed in proper engineering controls?		Click or tap here to enter text.
☐	☐	☐	101.	Does the entity have equipment dedicated to HD compounding?		Click or tap here to enter text.
☐	☐	☐	102.	Are bulk containers of liquid and API HD handled carefully to avoid spills?		Click or tap here to enter text.
☐	☐	☐	103.	Are APIs and powdered HDs handled in a C-PEC to protect against occupational exposure?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).	
Administering Are HDs administered at the facility? If HDs are administered by pharmacists at this facility, continue to question 104. If no, skip to question 111.						
☐	☐	☐	104.	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 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.	Click or tap here to enter text.
☐	☐	☐	105.	Is appropriate PPE worn when administering HDs?		Click or tap here to enter text.
☐	☐	☐	106.	Is PPE removed and disposed of in an approved HD waste container at the site of drug administration?		Click or tap here to enter text.
☐	☐	☐	107.	Are equipment and packaging materials disposed of properly after administration?		Click or tap here to enter text.
☐	☐	☐	108.	Are CSTDs used for administration of antineoplastic HDs when the dosage form allows?		Click or tap here to enter text.
☐	☐	☐	109.	Are techniques and ancillary devices that minimize risk from open systems used when administering HDs through certain routes?		Click or tap here to enter text.
☐	☐	☐	110.	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.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Deactivating, Decontaminating, Cleaning, and Disinfecting						
☐	☐	☐	111.	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 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.	Click or tap here to enter text.
☐	☐	☐	112.	Are sterile compounding areas and devices disinfected after cleaning?		Click or tap here to enter text.
☐	☐	☐	113.	Does the entity have written procedures for decontamination, deactivation, cleaning, and sterile compounding area disinfection?		Click or tap here to enter text.
☐	☐	☐	114.	Does cleaning of nonsterile compounding areas comply with <795> and cleaning of sterile compounding areas comply with <797>?		Click or tap here to enter text.
☐	☐	☐	115.	Do written procedures for cleaning include procedures, agents used, dilutions (if used), frequency, and documentation requirements?		Click or tap here to enter text.
☐	☐	☐	116.	Are personnel who perform deactivation, decontamination, cleaning, and disinfection in HD handling areas trained?		Click or tap here to enter text.
☐	☐	☐	117.	Do personnel wear appropriate PPE?		Click or tap here to enter text.
☐	☐	☐	118.	Are deactivating, decontaminating, cleaning, and disinfecting agents selected appropriate?		Click or tap here to enter text.
☐	☐	☐	119.	Are products used compatible with surface material?	**USP Chapter 800- 15 DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING**	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	120.	Does the disposal of materials meet EPA regulations and the entity's policies?	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.	Click or tap here to enter text.
☐	☐	☐	121.	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, 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).	Click or tap here to enter text.
☐	☐	☐	122.	Are products with known deactivation properties used whenever possible to deactivate residual HD compounds?		Click or tap here to enter text.
☐	☐	☐	123.	Are product labels unaltered by solutions used to wipe HD packaging?	**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.	Click or tap here to enter text.
☐	☐	☐	124.	Are work surfaces of the C-PEC decontaminated between compounding different HDs?		Click or tap here to enter text.
☐	☐	☐	125.	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?		Click or tap here to enter text.
☐	☐	☐	126.	Are areas under the work tray deactivated, decontaminated, and cleaned at least monthly in the C-PEC?		Click or tap here to enter text.
☐	☐	☐	127.	Are surfaces cleaned before disinfection?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	128.	Are areas that are intended to be sterile disinfected?	**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.	Click or tap here to enter text.
Spill Control						
☐	☐	☐	129.	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 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.	Click or tap here to enter text.
☐	☐	☐	130.	Are spills contained and cleaned immediately by qualified personnel with appropriate PPE?		Click or tap here to enter text.
☐	☐	☐	131.	Are qualified personnel available at all times while HDs are being handled?		Click or tap here to enter text.
☐	☐	☐	132.	Are signs available for restricting access to the spill area?		Click or tap here to enter text.
☐	☐	☐	133.	Are spill kits readily available in all areas where HDs are routinely handled?		Click or tap here to enter text.
☐	☐	☐	134.	If HDs are being prepared or administered in a non-routine healthcare area, is a spill kit and respirator available?		Click or tap here to enter text.
☐	☐	☐	135.	Are spill materials disposed of as hazardous waste?		Click or tap here to enter text.
☐	☐	☐	136.	Are the circumstances and management of spills documented?		Click or tap here to enter text.
			137.	Do HD SOPs include the following:		
☐	☐	☐	138.	a Spill prevention		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	138.	b	Direct the cleanup of spills		Click or tap here to enter text.
☐	☐	☐	138.	c	Address the size and scope of the spill		Click or tap here to enter text.
☐	☐	☐	138.	d	Specify who is responsible for spill management		Click or tap here to enter text.
☐	☐	☐	138.	e	Type of PPE required		Click or tap here to enter text.
☐	☐	☐	138.	f	Address the location of spill kits and clean-up materials		Click or tap here to enter text.
☐	☐	☐	138.	g	Capacity of the spill kit		Click or tap here to enter text.
Documentation and Standard Operating Procedures							
☐	☐	☐	139.		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.	Click or tap here to enter text.
☐	☐	☐	140.		Are the SOPs reviewed at least every 12 months by the designated person?		Click or tap here to enter text.
☐	☐	☐	141.		Is the SOP review documented?		Click or tap here to enter text.
☐	☐	☐	142.		Are revisions in forms or records made as needed and communicated to all personnel handling HDs?		Click or tap here to enter text.
☐	☐	☐	143.		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.	Click or tap here to enter text.

WA Pharmacy Quality Assurance Commission
2024 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 and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy or Hospital Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

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

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

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

Date responsible manager/change of responsible manager inspection was completed: Click or tap here to enter text.

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

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

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
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.	Click or tap here to enter text.
☐	☐	☐	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 recessed and difficult to access. One approach for disinfecting the vial septum in this type	Click or tap here to enter text.
☐	☐	☐	3.	If nonsterile components are used for sterile compounded preparations, is sterilization performed prior to dispensing?		Click or tap here to enter text.
☐	☐	☐	4.	If non-pyrogen-free components are used for sterile compounded preparations, is bacterial endotoxin testing performed prior to dispensing?		Click or tap here to enter text.
☐	☐	☐	5.	Are vial septa wiped with sterile 70% isopropyl alcohol prior to initial needle puncture?		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						of vial shield is to use right-angle forceps to hold a sterile 70% IPA wipe and apply direct contact with the vial septum. It is also acknowledged that such vial shields disrupt first air contacting the vial septum during certain handling conditions. Wipe the septum with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose container).	
RADIATION SAFETY CONSIDERATIONS							
			6.	Are aseptic handling practices balanced with radiation safety considerations, based on the following:		**USP Chapter 825– 2 RADIATION SAFETY CONSIDERATIONS** The handling of radiopharmaceuticals necessitates meeting the radiation regulatory agency requirements for worker safety. This involves licensing commitments to keep all exposure levels for the workers involved as low as reasonably achievable (ALARA) practices. Principles of radiation safety involve time, distance, shielding, and contamination control. Moreover, radiation detection and measuring devices are necessary. Aseptic handling practices must be balanced with radiation safety considerations, based on the following: Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions; The quantity of radioactivity, volume, handling steps, and timing; Other factors, which can vary on a case-by-case basis.	
☐	☐	☐	6.	a	Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions		Click or tap here to enter text.
☐	☐	☐	6.	b	The quantity of radioactivity, volume, handling steps, and timing		Click or tap here to enter text.
☐	☐	☐	6.	c	Other factors, which can vary on a case-by-case basis		Click or tap here to enter text.
☐	☐	☐	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. 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	Click or tap here to enter text.
☐	☐	☐	8.		Are policies implemented for handling biohazardous radioactive sharps while minimizing contamination?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					used to contain such radioactive contamination and, when used in an ISO Class 5 PEC, the pads must be clean and low-lint. Vertical air flow, not horizontal, in a PEC is used to control contamination. When exposure to blood and other potentially infectious material is reasonably anticipated, some engineered needlestick prevention devices may pose a radiation hazard to employees. Policies must be implemented for handling biohazardous radioactive sharps while minimizing contamination.	
☐	☐	☐	9.	Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?	**USP Chapter 825– 2.4 Radiation Contamination Control-RADIATION DETECTORS AND MEASURING DEVICES** Radiopharmaceuticals require measurement with a suitable radiation measuring device (e.g., dose calibrator). These and other necessary equipment, (e.g., monitors, bar code scanner, label printer) may be placed inside an ISO Class 5 PEC but should be placed in a manner that minimizes disruptions of airflow. As per RAM license requirements, individuals must wear body and, as required, extremity dosimeters (e.g., a ring worn on a finger) for long-term monitoring of personnel radiation exposure. The body dosimeter should be worn underneath the gown. Any extremity dosimeter must be worn underneath gloves and must not interfere with proper fit of gloves.	Click or tap here to enter text.
☐	☐	☐	10.	Are extremity dosimeters worn underneath gloves that do not interfere with proper fit of gloves?		Click or tap here to enter text.
IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS						
			11.	When preparing radiopharmaceuticals under immediate use practice 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	
☐	☐	☐	11.	a	Strict aseptic technique and limited beyond-use date must be adhered to given the lack of engineering controls.	Click or tap here to enter text.

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	11.	j	Follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling.	media fill challenge, gloved fingertip testing); While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (e.g., lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to. Dose splitting (splitting a unit dose for administration to more than one patient) may not be performed as immediate use; if performed, dose splitting must be done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area.	Click or tap here to enter text.
☐	☐	☐	11.	k	Follow 12.2 Labeling for labeling.		Click or tap here to enter text.
☐	☐	☐	11.	l	Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area during the time of use.		Click or tap here to enter text.
☐	☐	☐	11.	m	Does not require a segregated radiopharmaceutical processing area, classified area, or PEC.		Click or tap here to enter text.
☐	☐	☐	11.	n	The number of steps or punctures is not limited.		Click or tap here to enter text.
☐	☐	☐	11.	o	Does not require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications.		Click or tap here to enter text.
☐	☐	☐	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.		Click or tap here to enter text.
☐	☐	☐	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.		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE						
☐	☐	☐	12.	Are personnel trained to work with radiopharmaceuticals per the policies and SOPs authorized by an ANP or AU physician?	**USP Chapter 825– 4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE** Personnel must be trained to work with radiopharmaceuticals per the policies and standard operating procedures (SOPs) authorized by an ANP or AU physician. These individuals (e.g., nuclear medicine technologists or nuclear pharmacy technicians) must follow these policies and SOPs of the ANP or AU physician and work under their supervision. As appropriate, this should include blood-borne pathogens training. Individuals entering a compounding area must be properly garbed and must maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals. Individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (e.g., rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) must report these conditions to their supervisor. The designated person is responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved.	Click or tap here to enter text.
☐	☐	☐	13.	Do personnel follow the policies and SOPs of the ANP or AU physician?		Click or tap here to enter text.
☐	☐	☐	14.	Do personnel work under the supervision of the ANP or AU physician?		Click or tap here to enter text.
☐	☐	☐	15.	Are individuals entering the compounding area properly garbed?		Click or tap here to enter text.
☐	☐	☐	16.	Are individuals maintaining proper personal hygiene?		Click or tap here to enter text.
☐	☐	☐	17.	Do individuals who have a condition that may pose a higher potential of contamination with microorganisms report these conditions to their supervisor?		Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	19.	Are these qualifications completed and documented initially?		Click or tap here to enter text.
☐	☐	☐	20.	Are these qualifications completed and documented at repeated intervals?		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	21.	Are these qualifications completed and documented under the observation of a designated person?		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.	Click or tap here to enter text.
			22.	Do the qualifications include the following:			
☐	☐	☐	22.	a	Aseptic technique training with a documented assessment		Click or tap here to enter text.
☐	☐	☐	22.	b	Garbing and hand hygiene, as defined by the policies and SOPs		Click or tap here to enter text.
☐	☐	☐	22.	c	PEC cleaning and disinfecting		Click or tap here to enter text.
☐	☐	☐	22.	d	Gloved fingertip and thumb sampling		Click or tap here to enter text.
☐	☐	☐	22.	e	Media-fill testing		Click or tap here to enter text.
☐	☐	☐	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]	Click or tap here to enter text.
☐	☐	☐	24.	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?			Click or tap here to enter text.
☐	☐	☐	25.	Do touch plates or other devices contain general microbial growth agar supplemented with neutralizing additives?			Click or tap here to enter text.
☐	☐	☐	26.	Are gloves not disinfected immediately before touching the sampling device?			Click or tap here to enter text.
☐	☐	☐	27.	Are gloved fingertip and thumb samples from both hands collected by rolling finger pads and thumb pad over the agar surface, using a			Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				separate sampling device for each hand?		supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this supports both bacterial and fungal growth; Gloves must not be disinfected immediately before touching the sampling device, as this could cause a false-negative result; Using a separate sampling device for each hand, a gloved fingertip and thumb sample from both hands must be collected by rolling finger pads and thumb pad over the agar surface; The plates must be incubated in an incubator at 30°–35° for no less than 48 h, and then at 20°–25° for no less than 5 additional days.	
☐	☐	☐	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?			Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	30.	Does media-fill testing simulate the most challenging and stressful conditions encountered in the worker's duties?			Click or tap here to enter text.
			31.	Does media-fill testing meet the following:			
☐	☐	☐	31.	a	Are media-fill tests documented as defined by the facility's policies and SOPs?		Click or tap here to enter text.
☐	☐	☐	31.	b	Performed with a commercial source of soybean–casein digest medium		Click or tap here to enter text.
☐	☐	☐	31.	c	For sterile-to-sterile processing, activities start with sterile media		Click or tap here to enter text.
☐	☐	☐	31.	d	For nonsterile-to-sterile compounding, use a nonsterile soybean–casein digest powder to make a solution		Click or tap here to enter text.
☐	☐	☐	32.	Does the certificate of analysis include documentation of growth			Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				promotion testing for each lot of media used?		completed and the final containers are filled with the test medium, incubate media-filled containers in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms. Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days. In the event of failure, results of the evaluation and corrective actions must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, and the results.	
☐	☐	☐	33.	In the event of failure, are results of the evaluation and corrective actions documented?			Click or tap here to enter text.
☐	☐	☐	34.	Is the documentation maintained to provide a record and long-term assessment of personnel competency?			Click or tap here to enter text.
			35.	Does documentation meet the following:			
☐	☐	☐	35.	a	Name of the person evaluated		Click or tap here to enter text.
☐	☐	☐	35.	b	Evaluation date/time		Click or tap here to enter text.
☐	☐	☐	35.	c	Media and components used including manufacturer		Click or tap here to enter text.
☐	☐	☐	35.	d	Expiration date and lot number		Click or tap here to enter text.
☐	☐	☐	35.	e	Starting temperature for each interval of incubation		Click or tap here to enter text.
☐	☐	☐	35.	f	Dates of incubation		Click or tap here to enter text.
☐	☐	☐	35.	g	Results		Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	37.	Are all failures, retraining, and reevaluations documented?			Click or tap here to enter text.
☐	☐	☐	38.	Do personnel successfully complete requalification in the core competencies?		**USP Chapter 825– 4.2 Reevaluation, Retraining, and Requalification - REQUALIFICATION PROGRAM**	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	39.	Is successful completion demonstrated through observation, written testing, and hands-on demonstration of skills?	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.	Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	41.	Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months?		Click or tap here to enter text.
☐	☐	☐	42.	Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?		Click or tap here to enter text.
☐	☐	☐	43.	Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?		Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						but are required to complete all other training and testing. Other personnel or visitors (e.g., auditors, regulators, student observers) must comply with garbing and gloving SOPs but do not need to prove competency.	
			45.	For immediate use preparations, do precautions related to personal hygiene include the following:		**USP Chapter 825– 4.4 Hand Hygiene and Garbing for Immediate Use Preparations** Radiopharmaceuticals may be prepared and dispensed as immediate use, and the precautions related to personal hygiene to be followed must include the following: Hand hygiene: Wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands. Garbing: Immediately after hand hygiene, don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with 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		Click or tap here to enter text.
☐	☐	☐	45.	b	Garbing		Click or tap here to enter text.
☐	☐	☐	45.	c	Different lab coat worn for patient care than preparation		Click or tap here to enter text.
			46.	For activities in an ISO Class 5 PEC, precautions related to personal hygiene include the following:		**USP Chapter 825– 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area** In situations involving repackaging, dispensing, preparation, preparation with minor deviations, or compounding of sterile radiopharmaceuticals in an ISO Class 5 PEC, the following precautions related to personal hygiene are to be followed: Before entering the SRPA or buffer area, personnel must remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); all cosmetics; all hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection). Nail products (e.g., artificial nails, polish, extenders) are prohibited. Natural nails must be kept neat and trimmed. Remove ear buds and headphones. Radiation dosimetry devices are allowed, as required by the RAM license. Do not bring electronic devices that are not necessary for compounding	
☐	☐	☐	46.	a	Remove outer garments, cosmetics, exposed jewelry, and piercings that could interfere with garbing		Click or tap here to enter text.
☐	☐	☐	46.	b	Nail products prohibited		Click or tap here to enter text.
☐	☐	☐	46.	c	Natural nails kept neat and trimmed		Click or tap here to enter text.
☐	☐	☐	46.	d	Ear buds and headphones removed		Click or tap here to enter text.
☐	☐	☐	46.	e	Wash hands and arms up the elbows with soap and water for at least 30 seconds		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	46.	f	Dry hands using low-lint towels	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 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	Click or tap here to enter text.
☐	☐	☐	46.	g	Don shoe covers, head/hair/facial hair covers, and face mask		Click or tap here to enter text.
☐	☐	☐	46.	h	Don a low-lint gown with sleeves that fit snugly around the wrists and enclosed at the neck		Click or tap here to enter text.
☐	☐	☐	46.	i	Clean reusable gown donned daily		Click or tap here to enter text.
☐	☐	☐	46.	j	Aseptically don sterile, powder-free gloves		Click or tap here to enter text.
☐	☐	☐	46.	k	Gloves completely and snugly cover the ends of the gown cuffs		Click or tap here to enter text.
☐	☐	☐	46.	l	Periodically apply sterile 70% IPA to gloves		Click or tap here to enter text.
☐	☐	☐	46.	m	Routinely inspect the gloves for holes, punctures, radioactivity contamination, or tears		Click or tap here to enter text.
☐	☐	☐	46.	n	Immediately remove gloves if defective, radioactivity contamination, or malfunction and repeat antiseptic hand cleansing		Click or tap here to enter text.
☐	☐	☐	46.	o	Avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites		Click or tap here to enter text.
☐	☐	☐	46.	p	Upon exit of the SRPA or buffer area donned items are properly disposed of		Click or tap here to enter text.

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

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	53.	Are free-standing humidifiers/dehumidifiers and air conditioners not used within the classified area or SRPA?	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.	Click or tap here to enter text.
☐	☐	☐	54.	Are temperature and humidity monitoring devices verified for accuracy at least every 12 months or as required by the manufacturer?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	56.	Does the designated person ensure that ISO Class 5 PECs are located, operated, maintained, monitored, and certified to have appropriate air quality?		Click or tap here to enter text.
☐	☐	☐	57.	Are tacky surfaces not used in ISO-classified areas?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls -TYPES OF SECONDARY ENGINEERING CONTROLS AND DESIGN** Due to the interdependence of the various areas or areas that make up a sterile radiopharmaceutical processing facility, it is essential to define and control the dynamic interactions permitted between areas. When designing doors, consider the placement of door closures, door surfaces, and the movement of the door, all of which can affect airflow. Tacky surfaces must not be used in ISO-classified areas. The PEC must be located in a SEC, which may be either an ISO-classified buffer room with ante-room or an SRPA, in a manner that minimizes conditions that could increase the risk of microbial contamination.	Click or tap here to enter text.
☐	☐	☐	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.****		Click or tap here to enter text.
☐	☐	☐	59.	Are ISO-classified ante-rooms and buffer areas separated from surrounding unclassified areas of the facility with fixed walls and doors?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	60.	Are facility designs and controls in place to minimize flow of lower-quality air into more controlled areas?	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 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	Click or tap here to enter text.
☐	☐	☐	61.	Is air supplied to classified areas introduced through HEPA filters located in the ceiling?		Click or tap here to enter text.
☐	☐	☐	62.	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?		Click or tap here to enter text.
☐	☐	☐	63.	Are smoke studies of the PEC repeated when a change to the placement of the PEC is made within the area?		Click or tap here to enter text.
☐	☐	☐	64.	Are classified areas equipped with a pressure-differential monitoring system?		Click or tap here to enter text.
☐	☐	☐	65.	Do ante-rooms have a line of demarcation to separate the clean side from the less clean side?		Click or tap here to enter text.
☐	☐	☐	66.	Is required garb worn prior to crossing the line of demarcation?		Click or tap here to enter text.
☐	☐	☐	67.	Is the SRPA located away from unsealed windows, doors that connect to the outdoors, and traffic flow?		Click or tap here to enter text.
☐	☐	☐	68.	Is the impact of activities conducted around or adjacent to the SRPA considered when designing the area?		Click or tap here to enter text.
☐	☐	☐	69.	Does a visible perimeter establish the boundaries of the SRPA?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	70.	Is access to the SRPA restricted to authorized personnel and required materials?	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 the same time, which may be achieved using interlocking mechanisms.	Click or tap here to enter text.
☐	☐	☐	71.	Is the SRPA not located adjacent to environmental control challenges?		Click or tap here to enter text.
☐	☐	☐	72.	Are both pass-through doors never opened at the same time?		Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	74.	Are PECs designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic operating conditions?		Click or tap here to enter text.
☐	☐	☐	75.	Is airflow in PECs unidirectional?		Click or tap here to enter text.
☐	☐	☐	76.	Is HEPA-filtered air supplied in the direct processing area at a velocity sufficient to sweep particles away from aseptic processing areas?		Click or tap here to enter text.
☐	☐	☐	77.	Does HEPA-filtered air maintain unidirectional airflow during operations?		Click or tap here to enter text.

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

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					anteroom. ***See also Table 7. Preparation Conditions for Sterile Radiopharmaceuticals on Page 70 of this worksheet.*** A dynamic airflow smoke pattern test must be performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA.	
☐	☐	☐	84.	Is a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	**USP Chapter 825– 5.1 Facility Design and Environmental Controls - AIR-EXCHANGE REQUIREMENTS** For classified areas, adequate HEPA-filtered airflow to the buffer area(s) and ante-room(s) is required to maintain the appropriate ISO classification during processing activities. Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). The ACPH may need to be higher to maintain the required ISO classification and microbial state of control depending on these factors: the number of personnel permitted to work in the area, the number of particulates that may be generated from activities and processes in the area, the equipment located in the area, the area pressure, and the effects of temperature. The summary of ACPH requirements is listed in Table 2. A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 areas. The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7 under dynamic operating conditions considering factors listed above; At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling; The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH; If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance; The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on certification reports; A minimum of 20 ACPH of HEPA-filtered air must	Click or tap here to enter text.
☐	☐	☐	85.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 7 under dynamic operating conditions?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	87.	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?		Click or tap here to enter text.
☐	☐	☐	88.	Are the ACPH from HVAC, ACPH from the PEC, and total ACPH documented on certification reports?		Click or tap here to enter text.
☐	☐	☐	89.	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?		Click or tap here to enter text.
☐	☐	☐	90.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 8 under dynamic operating conditions?		Click or tap here to enter text.

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?	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.	Click or tap here to enter text.
☐	☐	☐	92.	Is the total ACPH documented on certification reports?		Click or tap here to enter text.
☐	☐	☐	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 sidewall. Classified areas should minimize dust-collecting overhangs such as utility pipes and ledges such as windowsills. If overhangs or ledges are present,	Click or tap here to enter text.
☐	☐	☐	94.	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices?		Click or tap here to enter text.
☐	☐	☐	95.	Is each inlaid ceiling panel caulked or otherwise sealed and secured?		Click or tap here to enter text.
☐	☐	☐	96.	Are walls constructed of or covered with a durable material?		Click or tap here to enter text.
☐	☐	☐	97.	Are walls constructed of or covered so the integrity of the surface is maintained?		Click or tap here to enter text.
☐	☐	☐	98.	Are panels joined together and sealed to each other and the support structure?		Click or tap here to enter text.
☐	☐	☐	99.	Do floors include coving to the sidewall?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	100.	Are junctures between the floor and walls caulked?	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.	Click or tap here to enter text.
☐	☐	☐	101.	Do floors include coving to the sidewall?		Click or tap here to enter text.
☐	☐	☐	102.	Are overhangs or ledges easily cleanable?		Click or tap here to enter text.
☐	☐	☐	103.	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?		Click or tap here to enter text.
☐	☐	☐	104.	Are penetrations through the ceiling or walls sealed?		Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	106.	Are overhangs or ledges easily cleanable?		Click or tap here to enter text.
☐	☐	☐	107.	Is the facility where sterile radiopharmaceuticals are prepared designed so that activities such as hand hygiene and garbing do not adversely affect the ability of the PEC to function as designed?	**USP Chapter 825– 5.3 Water Sources** The facility where sterile radiopharmaceuticals are prepared must be designed so that activities such as hand hygiene and garbing should not adversely affect the ability of the PEC to function as designed. Sinks should enable hands-free use with a closed system of soap (i.e.,	Click or tap here to enter text.

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?	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.	Click or tap here to enter text.
☐	☐	☐	109.	Does the buffer area not contain plumbed water sources?		Click or tap here to enter text.
☐	☐	☐	110.	Does the ante-room not contain floor drains?		Click or tap here to enter text.
☐	☐	☐	111.	In a facility with a SRPA design, is the sink accessible but located at least 1 m from the PEC and generators?		Click or tap here to enter text.
☐	☐	☐	112.	Is the sink not located inside the perimeter of the SRPA?		Click or tap here to enter text.
☐	☐	☐	113.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation not adversely impact environmental air quality?	**USP Chapter 825– 5.4 Placement and Movement of Materials** Only furniture, equipment, and other materials necessary are permitted in the classified area or SRPA and they should be low-shedding and easily cleaned and disinfected. Their number, design, location, and manner of installation must not adversely impact environmental air quality and must promote effective cleaning and disinfecting. No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the classified area or SRPA. Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels. All items must be wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-	Click or tap here to enter text.
☐	☐	☐	114.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation promote effective cleaning and disinfecting?		Click or tap here to enter text.
☐	☐	☐	115.	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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?	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.	Click or tap here to enter text.
☐	☐	☐	117.	Are carts cleaned and disinfected if they are moved from the clean side to the dirty side of the anteroom?		Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	119.	Are food, drinks, and materials kept out of patient care, treatment areas, ante-rooms, and buffer areas if exposed in patient care and treatment areas?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	121.	Are activities that require the manipulation of blood-derived or other biological material separated from routine material-handling procedures and equipment controlled by specific SOPs to avoid cross-contamination?		Click or tap here to enter text.
☐	☐	☐	122.	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements listed in	**USP Chapter 825– 5.6 Remote Aseptic Processing Involving a Hot-Cell**	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area?	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 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	
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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 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	Click or tap here to enter text.
☐	☐	☐	127.	Is there a mechanical system or SOP in place that ensures that both passthrough doors cannot be open at the same time?		Click or tap here to enter text.
☐	☐	☐	128.	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area?		Click or tap here to enter text.
☐	☐	☐	129.	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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 general environment outside the classified areas?	**USP Chapter 825– 5.7 Environmental Controls - ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS** Any time a pressure differential is required, a pressure monitoring device is required. In a classified area, a pressure differential monitoring system must be used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante-room and the general environment outside the classified area(s) or area(s). The results from the pressure monitoring system must be reviewed and documented at least daily on days the area is used. All pressure monitoring devices must be tested for accuracy and required performance at least every 6 months.	Click or tap here to enter text.
☐	☐	☐	131.	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?		Click or tap here to enter text.
☐	☐	☐	132.	Are all pressure monitoring devices tested for accuracy and performance at least every 6 months?		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			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		Click or tap here to enter text.
☐	☐	☐	133.	b	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals		Click or tap here to enter text.
☐	☐	☐	133.	c	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals		Click or tap here to enter text.
☐	☐	☐	134.	Is certification of the classified areas, including PECs, performed initially and at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline?		**USP Chapter 825– 5.7 Environmental Controls - CERTIFICATION OF PECS AND ENVIRONMENT IN WHICH THE PEC IS LOCATED** Certification of the classified areas, including the PEC, must be performed initially and recertification must be performed at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline, and must include the following: Airflow testing: To determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions; HEPA filter integrity testing: HEPA filters must be leak tested after installation and as part of recertification; Total particle counts testing: Conducted under dynamic operating conditions using calibrated electronic equipment; Smoke visualization studies: Performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). In cases where technologies exist for hot-cell and PEC	Click or tap here to enter text.
			135.	Does certification of the classified areas, including PECs, include the following:			
☐	☐	☐	135.	a	Airflow testing		Click or tap here to enter text.
☐	☐	☐	135.	b	HEPA filter integrity testing		Click or tap here to enter text.
☐	☐	☐	135.	c	Total particle counts testing		Click or tap here to enter text.
☐	☐	☐	135.	d	Smoke visualization studies		Click or tap here to enter text.
☐	☐	☐	136.	When technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards or other			Click or tap here to enter text.

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

MICROBIOLOGICAL AIR AND SURFACE MONITORING

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	141.	Are air and surface monitoring results and corrective actions documented?		Click or tap here to enter text.
☐	☐	☐	142.	Are records readily retrievable?		Click or tap here to enter text.
☐	☐	☐	143.	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	**USP Chapter 825– 6.1 General Monitoring Requirements** The goals of an air and surface monitoring program are to determine whether microbiological contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained. The microbiological air and surface monitoring program must include viable impact volumetric airborne particulate sampling and surface sampling. Air and surface sampling must be performed initially for classified areas in a facility to establish a baseline level of environmental quality. After initial sampling, the classified areas must be monitored according to the minimum frequencies described in this section to ensure that the environment remains in a suitable state for aseptic processing tasks. The air and surface monitoring program involves the collection and evaluation of samples from various air and surface locations to detect viable microbiological contaminants. The data are then used to assess risks for contamination,	Click or tap here to enter text.
☐	☐	☐	144.	Is air and surface sampling performed initially for classified areas in the facility?		Click or tap here to enter text.
☐	☐	☐	145.	After initial sampling, are the classified areas monitored according to the minimum frequencies?		Click or tap here to enter text.
☐	☐	☐	146.	Is regular review of the sampling data performed to detect trends?		Click or tap here to enter text.
☐	☐	☐	147.	Are results reviewed in conjunction with personnel data?		Click or tap here to enter text.
☐	☐	☐	148.	Is data reviewed following corrective actions?		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	149.		Is air and surface sampling conducted during actual or simulated dynamic operating conditions?	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 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	Click or tap here to enter text.
			150.		Is sampling performed in the following circumstances:		
☐	☐	☐	150.	a	In conjunction with the certification of new facilities and equipment		Click or tap here to enter text.
☐	☐	☐	150.	b	After any modification of facilities or equipment		Click or tap here to enter text.
☐	☐	☐	150.	c	In response to identified problems		Click or tap here to enter text.
☐	☐	☐	150.	d	In response to identified trends		Click or tap here to enter text.
☐	☐	☐	150.	e	In response to changes that could impact the controlled area environments		Click or tap here to enter text.
☐	☐	☐	150.	f	Is air and surface sampling conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	150.	h	Is the air and surface monitoring program described in the established SOPs of the facility?		Click or tap here to enter text.

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

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

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

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	163.	Are incubators used for microbiological testing placed in a location outside of any classified area or SRPA?		Click or tap here to enter text.
☐	☐	☐	164.	Are incubators used for microbiological testing kept away from areas where compounding or sterile processing activities are carried out?		Click or tap here to enter text.
☐	☐	☐	165.	Are sampling activities performed by trained individuals?		Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	167.	If two pieces of media were collected at a single location, are action levels applied individually to each plate/device?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.
☐	☐	☐	170.	Is a corrective action plan dependent on the cfu count and the microorganism recovered?		Click or tap here to enter text.
☐	☐	☐	171.	Is the corrective action plan documented?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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?	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).	Click or tap here to enter text.
☐	☐	☐	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.	Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	175.	Is each classified area sampled?		Click or tap here to enter text.
☐	☐	☐	176.	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?		Click or tap here to enter text.
☐	☐	☐	177.	Is surface sampling performed at the end of radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	178.	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?	microbial contamination. Surface sampling must be performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected. However, radiopharmaceutical personnel must also consider the appropriate exposure and contamination prevention measures prior to and while collecting samples. If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, measures must be taken to eliminate the risk (e.g., implementation of appropriate shielding, performing the sampling at a later time or alternate day).	Click or tap here to enter text.
☐	☐	☐	179.	If the worker assesses that risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk?		Click or tap here to enter text.
☐	☐	☐	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	Click or tap here to enter text.
☐	☐	☐	181.	Do CoAs from the manufacturer verify that the media meets expected growth promotion, pH, and sterilization requirements?		Click or tap here to enter text.
☐	☐	☐	182.	Do surface sampling devices contain general microbial growth media supplemented with neutralizing additives?		Click or tap here to enter text.
☐	☐	☐	183.	If used, do contact plates have a raised convex surface?		Click or tap here to enter text.
☐	☐	☐	184.	After sampling, is the sampled area cleaned and disinfected?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (i.e., surface). Include sample location and date. 4. Incubate the device at 20°–25° for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (i.e., surface). Include sample location and date. Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location. 1. Both samples could be TSA or one sample could be TSA and the other fungal media (e.g., MEA or SDA). 2. Incubate each sample in a separate incubator. Incubate one sample at 30°–35° for no less than 48 hours, and incubate the other sample at 20°–25° for no less than 5 days. 3. If fungal media are used as one of the samples, incubate the fungal media sample at 20°–25° for no less than 5 days. 4. Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample. Record the results of the sampling. 5. Record the results of the sampling.	
☐	☐	☐	185.	If two devices were collected at a single location, is all recovered growth on each documented?	**USP Chapter 825– 6.3 Monitoring Surfaces for Viable - DATA EVALUATION AND ACTION LEVELS** Evaluate cfu counts against the action levels in Table 4 and examine counts in relation to previous data to identify adverse results or trends. If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each piece of media individually (i.e., results from each sampling device must be compared to the action level for the area). If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. Data	Click or tap here to enter text.
☐	☐	☐	186.	If two devices were collected at a single location, are action levels applied to each piece of media individually?		Click or tap here to enter text.
☐	☐	☐	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?		Click or tap here to enter text.

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?	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).	Click or tap here to enter text.
☐	☐	☐	189.	Is data collected in response to corrective actions reviewed?		Click or tap here to enter text.
☐	☐	☐	190.	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		Click or tap here to enter text.
☐	☐	☐	191.	Is the corrective action plan documented?		Click or tap here to enter text.
☐	☐	☐	192.	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?		Click or tap here to enter text.
CLEANING AND DISINFECTING						
☐	☐	☐	193.	Are surfaces cleaned prior to being disinfected? ****Using an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner to accomplish both the cleaning and disinfection in one step is acceptable.****	**USP Chapter 825-7 CLEANING AND DISINFECTING** Cleaning and disinfecting are important because surfaces in classified areas and SRPAs are a potential source of microbial contamination of sterile radiopharmaceuticals. The process of cleaning involves removing organic and inorganic residues from surfaces, usually with a manual or mechanical process and a cleaning agent. The process of disinfecting involves destruction of microorganisms, usually with a chemical or physical agent. Surfaces must be cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one	Click or tap here to enter text.
☐	☐	☐	194.	If sterile processing of radiopharmaceuticals are not performed daily, is cleaning and disinfecting completed before initiating these activities?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	195.	Is reducing or removing radioactivity from an object or surface balanced with the risk of spreading radioactive contamination?	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.	Click or tap here to enter text.
☐	☐	☐	196.	Is the balance of reducing or removing radioactivity from an object or surface and risk of spreading radioactive contamination specified in SOPs?		Click or tap here to enter text.
☐	☐	☐	197.	Are cleaning and disinfecting activities performed by trained and appropriately garbed personnel?		Click or tap here to enter text.
☐	☐	☐	198.	Are cleaning and disinfecting activities performed using facility-approved agents?		Click or tap here to enter text.
☐	☐	☐	199.	Are cleaning and disinfecting activities performed using procedures described in written SOPs?		Click or tap here to enter text.
☐	☐	☐	200.	Is cleaning performed in the direction of most to least clean areas?		Click or tap here to enter text.
☐	☐	☐	201.	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?		Click or tap here to enter text.
☐	☐	☐	202.	Are written SOPs followed by cleaning personnel?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	203.	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?		Click or tap here to enter text.
☐	☐	☐	204.	When sterile 70% IPA is used, is it allowed to dry?		Click or tap here to enter text.
☐	☐	☐	205.	Is cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?		Click or tap here to enter text.
☐	☐	☐	206.	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* <1072>). After the disinfectant is applied on the surface to be disinfected, the disinfectant must be allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed. Only the 70% IPA used in the ISO Class 5 PEC must be sterile. Sporicidal agents must be used at least monthly on all surfaces in classified areas and SRPAs. Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties. See Table 6 for a summary of the purpose of the cleaning, disinfecting, and sporicidal agents.	Click or tap here to enter text.
☐	☐	☐	207.	Is the disinfectant allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer without being disturbed?		Click or tap here to enter text.
☐	☐	☐	208.	Is sterile 70% IPA used in the ISO Class 5 PEC?		Click or tap here to enter text.
☐	☐	☐	209.	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?		Click or tap here to enter text.
☐	☐	☐	210.	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-	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	211.	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).	Click or tap here to enter text.
☐	☐	☐	212.	Are reusable cleaning tools made of cleanable materials?		Click or tap here to enter text.
☐	☐	☐	213.	Are reusable cleaning tools cleaned and disinfected before and after each use?		Click or tap here to enter text.
☐	☐	☐	214.	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and not removed from these areas except for disposal?		Click or tap here to enter text.
☐	☐	☐	215.	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?		Click or tap here to enter text.
☐	☐	☐	216.	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?	**USP Chapter 825– 7.3 Cleaning and Disinfecting the PEC** Clean and disinfect the PEC at the minimum frequencies specified in Table 5. If the PEC contains a removable work tray, all sides of the work tray and the area underneath the work tray must be cleaned and disinfected at least monthly. 1. Survey all surfaces of the PEC for radioactive contamination and follow facility SOPs to decontaminate, if necessary. 2. Remove, if necessary, any particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers. 3. Apply a cleaning agent followed by a disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved. 4. Apply sterile 70% IPA 5. Allow the surface to dry completely before beginning activities. 6. The PEC must be wiped with a sporicidal agent at least monthly.	Click or tap here to enter text.
☐	☐	☐	217.	Is the PEC wiped with a sporicidal agent at least monthly?		Click or tap here to enter text.
☐	☐	☐	218.	Are all shipping carton(s), corrugated or uncoated cardboard	**USP Chapter 825– 7.4 Disinfecting Supplies for Classified Areas and SRPAs**	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				kept out of the classified areas and kept out of the perimeter of the SRPA?	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.	
☐	☐	☐	219.	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?		Click or tap here to enter text.
☐	☐	☐	220.	Are sporicidal or sterile disinfectant agents allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer?		Click or tap here to enter text.
☐	☐	☐	221.	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		Click or tap here to enter text.
☐	☐	☐	222.	Is each item transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant?		Click or tap here to enter text.
☐	☐	☐	223.	Are critical sites wiped with sterile 70% IPA?	**USP Chapter 825-7.5 Disinfecting Critical Sites** Critical sites (e.g., vial stoppers) must be wiped with sterile 70% IPA. The critical site must be wiped ensuring that both chemical and mechanical actions are used to remove contaminants. The sterile 70% IPA must be allowed to dry before piercing critical sites.	Click or tap here to enter text.
☐	☐	☐	224.	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?		Click or tap here to enter text.
☐	☐	☐	225.	Is sterile 70% IPA allowed to dry before piercing critical sites?		Click or tap here to enter text.
☐	☐	☐	226.	Are radiation shielding and equipment that is exposed to patient care areas during the	**USP Chapter 825– 7.6 Cleaning and Disinfecting Items from Patient Care Area**	Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				process of administration cleaned and disinfected before returning to any classified area or SRPA?		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.	
☐	☐	☐	227.	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.****			Click or tap here to enter text.
☐	☐	☐	228.	Is equipment cleaned and disinfected through actions regulated by the facilities' SOPs?			Click or tap here to enter text.
☐	☐	☐	229.	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?			Click or tap here to enter text.
ASSIGNING BUD							
☐	☐	☐	230.	If assigning a BUD longer than the manufacturer-stated/suggested use-by time interval, is there evidence to support the maintenance of appropriate quality and purity?		**USP Chapter 825– 8. Assigning BUD** BUDs are based on the risk of microbial contamination with the assumption that the radiopharmaceutical(s) should remain chemically and physically stable, and its container–closure system should maintain its integrity for the duration of the BUD (Table 7). The time starts at the moment of the first sterile vial puncture or exposure of a critical site (e.g., syringe tip, needle hub, or needle) to ambient air, whichever is first. The BUDs stated in Table 7 are maximum values in the absence of sterility testing, and the assigned BUD may be shorter for a variety of reasons discussed below. The individual responsible for the manipulation assigns the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature. For compounded preparations (sterile and nonsterile), the BUD	Click or tap here to enter text.
			231.	When assigning a BUD for a radiopharmaceutical(s), are the following considered:			
☐	☐	☐	231.	a	Sterility		Click or tap here to enter text.
☐	☐	☐	231.	b	Radiochemical purity where the assigned BUD is based on stability studies		Click or tap here to enter text.

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

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

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
DOCUMENTATION							
☐	☐	☐	233.	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.	Click or tap here to enter text.
			234.	Is the following data included in the MFR when a minor deviation or compounding occurs:		**USP Chapter 825– 9.1 Master Formulation Record** A MFR is required only for a preparation with minor deviations or compounding, as described in 11. Compounding. A MFR is not required for a preparation following the manufacturer's instructions. Data that must be included in the MFR are as follows: Name of the radiopharmaceutical; Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA); Detailed procedure (e.g., heating, components, incubation time); Range of	
☐	☐	☐	234.	a	Name of the radiopharmaceutical		Click or tap here to enter text.
☐	☐	☐	234.	b	Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	234.	c	Detailed procedure	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.	Click or tap here to enter text.
☐	☐	☐	234.	d	Range of radioactivity		Click or tap here to enter text.
☐	☐	☐	234.	e	Range of volume		Click or tap here to enter text.
☐	☐	☐	234.	f	Equipment to be used		Click or tap here to enter text.
☐	☐	☐	234.	g	PEC and SEC to be used		Click or tap here to enter text.
☐	☐	☐	234.	h	Quality control tests to be performed for final release of the radiopharmaceutical		Click or tap here to enter text.
☐	☐	☐	234.	i	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits		Click or tap here to enter text.
☐	☐	☐	234.	j	Trained personnel		Click or tap here to enter text.
☐	☐	☐	234.	k	Garbing procedure, if different than standard procedure		Click or tap here to enter text.
☐	☐	☐	234.	l	Container(s)		Click or tap here to enter text.
☐	☐	☐	234.	m	Reference source of the BUD assignment and storage conditions		Click or tap here to enter text.
			235.	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	
☐	☐	☐	235.	a	Name of the radiopharmaceutical		Click or tap here to enter text.
☐	☐	☐	235.	b	Physical form		Click or tap here to enter text.
☐	☐	☐	235.	c	Name and quantity of ingredients including calibration time for radioactive ingredients		Click or tap here to enter text.
☐	☐	☐	235.	d	Total volume		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	235.	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.	Click or tap here to enter text.
☐	☐	☐	235.	f	Any deviation from the MFR, if applicable		Click or tap here to enter text.
☐	☐	☐	235.	g	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components		Click or tap here to enter text.
☐	☐	☐	235.	h	Name of the person who prepared and name of the supervising personnel		Click or tap here to enter text.
☐	☐	☐	235.	i	Date and time of preparation		Click or tap here to enter text.
☐	☐	☐	235.	j	Assigned internal identification number		Click or tap here to enter text.
☐	☐	☐	235.	k	Unique reference [e.g., prescription, order number(s)]		Click or tap here to enter text.
☐	☐	☐	235.	l	Assigned BUD and storage requirements		Click or tap here to enter text.
☐	☐	☐	235.	m	Documentation of QC results		Click or tap here to enter text.
PREPARATION							
☐	☐	☐	236.		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.	Click or tap here to enter text.
☐	☐	☐	237.		Do deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions?	**USP Chapter 825– 10.2 Preparation with Minor Deviations** In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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.	
☐	☐	☐	238.	Are blood and blood components handled with required precautions using aseptic technique?	**USP Chapter 825– 10.3 Preparation of Radiolabeled Blood Components** Handling blood and radiolabeling of blood components requires special attention to biological risks and must be handled with standard precautions using aseptic technique to prevent the introduction of new	Click or tap here to enter text.
☐	☐	☐	239.	Are blood sample preparations administered within 6 hours of receipt?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	240.	Is there complete physical separation between where blood products are handled and non-blood products?	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 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	Click or tap here to enter text.
☐	☐	☐	241.	Are blood products labeled in ISO Class 5 BSC in an ISO Class 7 buffer area?		Click or tap here to enter text.
☐	☐	☐	242.	If more than one ISO class 5 PEC is located within the ISO Class 7 buffer area, are policies and SOP's in place?		Click or tap here to enter text.
☐	☐	☐	243.	Are certifications in place that the SEC meets air quality at maximum occupancy under dynamic operating conditions?		Click or tap here to enter text.
☐	☐	☐	244.	Is there only one radiolabeling procedure per PEC at a time?		Click or tap here to enter text.
☐	☐	☐	245.	Are blood products from only one patient manipulated at each workstation at a time?		Click or tap here to enter text.
☐	☐	☐	246.	If a dedicated dose calibrator is not available, is a dedicated dose calibrator available to prevent the blood containers from contaminating the calibrator?		Click or tap here to enter text.
☐	☐	☐	247.	If a dedicated dose calibrator is not available, are dose calibrator dippers and liners cleaned and disinfected prior to the radioassay?		Click or tap here to enter text.
☐	☐	☐	248.	Are all tubes and syringes in contact with patient blood components clearly labeled?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	249.	Do SOP's address cleaning and disinfection process as required for blood-borne pathogens?	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.	Click or tap here to enter text.
			250.	Is in vitro red blood cell labeling prepared under the following conditions:	**USP Chapter 825-10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use** In vitro red blood cell labeling must be prepared while following the conditions below: A dedicated space for blood handling must be designated through the entirety of the blood radiolabeling process. This area must be free from clutter and not used for any other	
☐	☐	☐	250.	a A dedicated space for blood handling throughout the entirety of the blood radiolabeling process		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	250.	b	Area free from clutter and not used for any other preparations or handling prior to cleaning and disinfection	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).	Click or tap here to enter text.
☐	☐	☐	250.	c	Only one procedure labeled at a time or a documented process to maintain integrity of samples and environment		Click or tap here to enter text.
☐	☐	☐	250.	d	Equipment dedicated for radiolabeling procedure		Click or tap here to enter text.
☐	☐	☐	250.	e	Prevention of blood containers contaminating a dose calibrator if a dedicated dose calibrator is not available		Click or tap here to enter text.
☐	☐	☐	250.	f	Dose calibrator cleaned and disinfected if a dedicated calibrator is not available		Click or tap here to enter text.
☐	☐	☐	250.	g	Procedure for cleaning and disinfecting with appropriate products used to decontaminate the dipper and liner of the dose calibrator following the radioassay		Click or tap here to enter text.
☐	☐	☐	250.	h	Cleaning and disinfecting procedure followed to decontaminate the area and equipment prior to and after the radiolabeling is complete		Click or tap here to enter text.
☐	☐	☐	250.	i	Hand hygiene and garbing for immediate use followed		Click or tap here to enter text.
☐	☐	☐	250.	j	The start time of the preparation begins with initial container puncture or exposure of critical site		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	250.	k	A BUD of 1 hour is used for expiration		Click or tap here to enter text.
COMPOUNDING							
☐	☐	☐	251.		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.	Click or tap here to enter text.
☐	☐	☐	252.		Are there written procedures for maintenance of compounding records that provide traceability?		Click or tap here to enter text.
☐	☐	☐	253.		Is sterile compounding performed in an ISO 5 PEC?		Click or tap here to enter text.
☐	☐	☐	254.		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?		Click or tap here to enter text.
☐	☐	☐	255.		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?		Click or tap here to enter text.
☐	☐	☐	256.		Are areas designated for nonsterile compounding clean, uncluttered, and separated from sterile radiopharmaceuticals?	**USP Chapter 825-11.1 Compounding Nonsterile Radiopharmaceuticals** Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical. Examples of compounding nonsterile radiopharmaceuticals include:	Click or tap here to enter text.
☐	☐	☐	257.		Does the placement of equipment and materials take into account a design that prevents cross-contamination?		Click or tap here to enter text.

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
☐	☐	☐	258.			Does each compound have a unique MFR?	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 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	Click or tap here to enter text.
☐	☐	☐	259.			Are the ingredients obtained from the preferred sources?		Click or tap here to enter text.
☐	☐	☐	260.			Does the MFR detail ingredients obtained from other sources that are suitable for the intended use?		Click or tap here to enter text.
			261.			Does the MFR establish the following for non-preferred sources by validated means:		
☐	☐	☐	261.	a		Identity		Click or tap here to enter text.
☐	☐	☐	261.	b		Strength		Click or tap here to enter text.
☐	☐	☐	261.	c		Purity		Click or tap here to enter text.
☐	☐	☐	261.	d		Quality		Click or tap here to enter text.
☐	☐	☐	262.			Are BUD's for the compounded radiopharmaceuticals validated?		Click or tap here to enter text.
☐	☐	☐	263.			Does the BUD not extend past the shortest BUD of any components?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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.	
☐	☐	☐	264.	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.	Click or tap here to enter text.
☐	☐	☐	265.	Does the individual responsible consider all the possible interactions and alteration of stability for kit components if kit-splitting is used?		Click or tap here to enter text.
☐	☐	☐	266.	If nonsterile components are used is a sterilization and testing procedure performed?	**USP Chapter 825-11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components** Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides. If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (e.g., filtration with bubble point testing) and testing described in (85) must be performed. The designated person for	Click or tap here to enter text.
☐	☐	☐	267.	Does the designated person for compounding consider all possible interactions between components, such as stability, radiochemical stability, solubility, and other parameter?		Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	268.	Does compounding of bulk drug substances comply with USP and NF monograph standards?	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.	Click or tap here to enter text.
☐	☐	☐	269.	Does compounding with excipients or other inactive ingredients comply with USP and NF monograph standards?		Click or tap here to enter text.
☐	☐	☐	270.	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.	Click or tap here to enter text.
☐	☐	☐	271.	Is the activity at calibration within limits?		Click or tap here to enter text.

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	273.	h	Route of administration		Click or tap here to enter text.
Direct Infusion Systems – Pharmacies that do not utilize Direct Infusion Systems and answer "No" to question 274 may skip question numbers 275-278							
☐	☐	☐	274.		Does the facility use radiopharmaceutical direct infusion systems under the guidelines that are described in USP <825> 12.3?	**USP Chapter 825-12.3 Direct Infusion Systems** The information in this section is limited to the sterility and aseptic technique for direct infusion systems. The described infusion systems are FDA-cleared medical devices or FDA-approved direct infusion generators without an ISO-5 environment. The manner in which all necessary solutions (e.g., radiopharmaceutical and eluant/diluent) are used in conjunction with the system was a consideration in the overall approval process for the system. Therefore, all operators of the direct infusion systems must follow the "Instructions for Use" in the device labeling. Direct infusion generators (e.g., rubidium chloride Rb 82 injection) may employ a container of eluant (e.g., bag of 0.9% sodium chloride injection) to allow administration of the eluate directly to patient(s); Direct infusion devices (e.g., portable PET patient-infusion system) provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical (e.g., fludeoxyglucose F 18 injection) and the diluent (e.g., 0.9% sodium chloride injection) directly to patients to reduce the radiation exposure to personnel. In each of these situations, the radiopharmaceutical container must be attached to or be needle-punctured by the respective direct infusion system. Given that such direct infusion systems are intended for multiple patients over the course of several hours, there could be a sterility concern if not operated properly. Therefore, the following parameters must be considered by the operator of the system: Setup attachment or needle-puncture should be performed in a defined	Click or tap here to enter text.
☐	☐	☐	275.		Do all operators of the direct infusion systems follow the "Instructions for Use" in the device labeling?		Click or tap here to enter text.
			276.		In the following situations, is the radiopharmaceutical container attached to or needle-punctured by the respective direct infusion system:		
☐	☐	☐	276.	a	Direct infusion generators that employ a container of eluant to allow administration of the eluate directly to patient(s)		Click or tap here to enter text.
☐	☐	☐	276.	b	Direct infusion devices that provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical directly to patients to reduce the radiation exposure to personnel		Click or tap here to enter text.
			277.		Are the following parameters considered by the operator of the system if it is intended for multiple patients over the course of several hours:		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	277.	a	Setup attachment or needle-puncture should be performed in a defined environment	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.	Click or tap here to enter text.
☐	☐	☐	277.	b	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table 7)		Click or tap here to enter text.
☐	☐	☐	277.	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		Click or tap here to enter text.
☐	☐	☐	277.	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		Click or tap here to enter text.
☐	☐	☐	277.	e	The septum of any vial and the ports of any diluent bag must be wiped with sterile 70% IPA prior to puncturing		Click or tap here to enter text.
☐	☐	☐	277.	f	When puncturing the vial in ambient air, it must only be punctured once		Click or tap here to enter text.
☐	☐	☐	277.	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		Click or tap here to enter text.

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			278.	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.	
☐	☐	☐	278.	a	The generator needle and/or ports capped in ISO Class 8 air or better with sterile protectors		Click or tap here to enter text.
☐	☐	☐	278.	b	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system		Click or tap here to enter text.
REPACKAGING							
☐	☐	☐	279.	Are opened or repackaged radiopharmaceuticals radioassayed?		**USP Chapter 825-13 REPACKAGING** Repackaging refers to the act of removing conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients. Repackaging may be performed for nonsterile radiopharmaceuticals (e.g., I-131 sodium iodide oral capsules) and for sterile radiopharmaceuticals (e.g., thallous chloride Tl 201 injection). Except for unopened manufacturer dosage units (e.g., capsules, Xe-133 vials), the repackaged radiopharmaceutical must be radioassayed (i.e., in a dose calibrator). The inner container should be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; The radionuclide and chemical form (generic name); Radioactivity with units at time of calibration and the calibration time The outer shielding should be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive 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),	Click or tap here to enter text.

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	285.	Does the facility have SOPs if a radiopharmaceutical is dispensed or administered before the results of release testing are known?		**USP Chapter 825-14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals** If a radiopharmaceutical is dispensed or administered before the results of release testing are known, the facility must have SOPs in place to: 1. Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes), and 2. Determine whether a recall is necessary. The SOP for recall of out-of-specification dispensed radiopharmaceuticals must contain procedures to: Determine the severity of the problem and the urgency for the implementation and completion of the recall; Determine the distribution of any affected radiopharmaceutical, including the date and quantity; Identify patients who have received the radiopharmaceutical; Outline the disposition and reconciliation of the recalled radiopharmaceutical The facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (e.g., state board of pharmacy, state health department).	Click or tap here to enter text.
			286.	Does the facility's SOPs include the following:			
☐	☐	☐	286.	a	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm		Click or tap here to enter text.
☐	☐	☐	286.	b	Determine whether a recall is necessary		Click or tap here to enter text.
			287.	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain procedures to:			
☐	☐	☐	287.	a	Determine the severity of the problem and the urgency for the implementation and completion of the recall		Click or tap here to enter text.
☐	☐	☐	287.	b	Determine the distribution of any affected radiopharmaceutical, including the date and quantity		Click or tap here to enter text.
☐	☐	☐	287.	c	Identify patients who have received the radiopharmaceutical		Click or tap here to enter text.
☐	☐	☐	287.	d	Outline the disposition and reconciliation of the recalled radiopharmaceutical		Click or tap here to enter text.
☐	☐	☐	288.	Does the facility document the implementation of recall procedures?			Click or tap here to enter text.

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

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	296.	d	The response to the complaint	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.	Click or tap here to enter text.
☐	☐	☐	296.	e	The name and strength of the radiopharmaceutical (if known)		Click or tap here to enter text.
☐	☐	☐	296.	f	The assigned internal identification number		Click or tap here to enter text.
☐	☐	☐	296.	g	The findings of any investigation		Click or tap here to enter text.
☐	☐	☐	296.	h	Any follow-up of any investigation		Click or tap here to enter text.
☐	☐	☐	297.		Are records of complaints retrievable for review and evaluation for a possible trend?		Click or tap here to enter text.
☐	☐	☐	298.		Are records of complaints retained in accordance with the record keeping requirements in 9. Documentation?		Click or tap here to enter text.
☐	☐	☐	299.		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?		Click or tap here to enter text.
☐	☐	☐	300.		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).	Click or tap here to enter text.

Table 7. Preparation Conditions for Sterile Radiopharmaceuticals[1]

Preparation Conditions			
Manipulation	**PEC**	**SEC**	**BUD (hours)**
Immediate use	--	--	1
Direct infusion system, one puncture only (e.g., PET patient infusion system, Rb-82 generator)	--	--	10
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	SRPA	12
Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	SRPA with ISO Class 8 total airborne particle count	12
Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using sterile components	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	96
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using a nonsterile component and performing sterilization procedure (e.g., filtration with bubble point testing) but without performing *Sterility Tests* (71) testing	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	24
Radiolabeled blood components for immediate use [e.g., Tc 99m red blood cells (RBC)]	--	--	1
Radiolabeled blood components (e.g., radiolabeled leukocytes)	ISO Class 5 BSC	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	6 h after the blood sample is obtained

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

Washington State Department of Health

Read this Page Carefully

Pharmacy Quality Assurance Commission
2024 Wholesaler Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

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

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

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

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

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

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

Wholesaler Self-Inspection Worksheet

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

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

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

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

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

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

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

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

Endorsements: ☐ Controlled Substances ☐ Export Wholesaler

Document and Record Review

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

	Rule Reference
Wholesaler Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Wholesaler License Location: Click or tap here to enter text.	**RCW 18.64.046(1)** "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified…"
DEA Registration Location: Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**21 CFR 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (3) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." **WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."

Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft…"
Suspicious Order Reports Location: Click or tap here to enter text. **Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.** **Exemption Attestation**	**WAC 246-945-585(1)** "(a)Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to:(i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(b)** "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." **21 CFR 1305.13(d)** "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." **21 CFR 1305.13(e)** "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1.	Does the wholesaler have a current license?	**RCW 18.64.046(1)** "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified for the period ending on a date to be determined by the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business." **WAC 246-945-246(1)** "Every wholesaler who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes: (a) In-state and out-of-state pharmaceutical wholesalers; (b) Out-of-state manufacturer that distribute or sell drugs into Washington; (c) Virtual wholesalers; (d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington; (e) Outsourcing facilities required to be registered with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) that are located in Washington, or distribute or sell drugs into Washington; and (f) Reverse distributors."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	2.	Does the wholesaler have a current DEA registration?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
General Standards						
☐	☐	☐	3.	Does the wholesaler maintain a current list of all persons responsible for drug access, distribution, handling, and their training?	**WAC 246-945-580** "(1) A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (2) A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities."	Click or tap here to enter text.
☐	☐	☐	4.	Is the facility appropriately constructed and equipped to accommodate cleaning, maintenance, and operations?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations…"	Click or tap here to enter text.
☐	☐	☐	5.	Does the facility have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (b) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security…" **WAC 246-945-565(2)** "If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected."	Click or tap here to enter text.
☐	☐	☐	6.	Does the facility have a quarantine area for drugs that are unsuitable for distribution?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;…"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					WAC 246-945-565 (5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards."	
☐	☐	☐	7.	Is the facility maintained in a clean and orderly condition?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (d) Be maintained in a clean and orderly condition;…"	Click or tap here to enter text.
☐	☐	☐	8.	Is the facility free from infestation?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (e) Be free from infestation of any kind;…"	Click or tap here to enter text.
☐	☐	☐	9.	Is the facility a commercial location?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (f) Be a commercial location and not a personal dwelling or residence;	Click or tap here to enter text.
☐	☐	☐	10.	Does the facility have secure and confidential storage of information?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information;…"	Click or tap here to enter text.
☐	☐	☐	11.	Does the facility have a method of inventory control to detect theft, counterfeiting, or drug diversion?	**WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (h) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs."	Click or tap here to enter text.
☐	☐	☐	12.	Is the outside of the facility well-lit and is it appropriately secured with limited access?	**WAC 246-945-560(2)** "Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (a) Access from outside the premises must be kept to a minimum and well controlled;	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(b) The outside perimeter of the premises must be well lit; (c) Entry into areas where drugs are held must be limited to authorized personnel; (d) Facilities must be equipped with an alarm system to detect entry after hours; and (e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering."	
☐	☐	☐	13.	Does the facility have temperature and humidity monitoring devices? **Must follow 2-year recordkeeping requirements**	**WAC 246-945-565(3)** "Temperature and humidity recording equipment, devices, and/or logs shall be used to document proper storage of drugs."	Click or tap here to enter text.
☐	☐	☐	14.	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? ** Electronic monitoring is acceptable. **	**WAC 246-945-565 Wholesaler—**Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF), to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Re-questors may also contact USP directly to obtain copies.	Click or tap here to enter text.
☐	☐	☐	15.	Are freezers between -25°& -10°C (-13° & 14°F)?	**WAC 246-945-565 Wholesaler—**Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF), to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Re-questors may also contact USP directly to obtain copies.	Click or tap here to enter text.
☐	☐	☐	16.	Are controlled substances stored separately from noncontrolled substances and secured?	**WAC 246-945-565(4)** "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." ***See 21 CFR 1301.72 for the requirements for transferring controlled substance prescriptions.**	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	17.	Are shipments inspected upon arrival and prior to departure from the facility?	**WAC 246-945-570** "(1) Each outside shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. (2) Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents."	Click or tap here to enter text.
☐	☐	☐	18.	Does the facility verify that the person they purchase drug stock from is authorized to distribute drugs?	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs to that purchaser or recipient…"	Click or tap here to enter text.
☐	☐	☐	19.	Does the facility verify that the person to whom they distribute is authorized to receive drug stock?	**WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug…"	Click or tap here to enter text.

Policies and Procedures

Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets and binders).

			20.	Does the wholesaler have policies and procedures in place for the following:	**WAC 246-945-590** "Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures: (1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:	
☐	☐	☐	20.	a Receipt		Click or tap here to enter text.
☐	☐	☐	20.	b Security		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	20.	c	Storage	(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or (b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market. (2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency. (3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs. (4) A procedure for the destruction of outdated drugs in accordance with federal and state laws. (5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements. (6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies as required to the FDA, commission and/or appropriate federal or state agency upon discovery of such discrepancies. (7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA. (8) Procedures addressing:	Click or tap here to enter text.
☐	☐	☐	20.	d	Inventory		Click or tap here to enter text.
☐	☐	☐	20.	e	Transport		Click or tap here to enter text.
☐	☐	☐	20.	f	Shipping		Click or tap here to enter text.
☐	☐	☐	20.	g	Report of losses		Click or tap here to enter text.
☐	☐	☐	20.	h	Inventory records		Click or tap here to enter text.
☐	☐	☐	20.	i	Recalls		Click or tap here to enter text.
☐	☐	☐	20.	j	Staff training		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	20.	k	Suspicious order monitoring	(a) The design and operation of the suspicious order monitoring and reporting system; (b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following: (i) The wholesaler's suspicious order monitoring system; (ii) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and (iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities. (9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs." **WAC 246-945-560(1)** "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information…"	Click or tap here to enter text.
☐	☐	☐	20.	l	Emergent need		Click or tap here to enter text.
☐	☐	☐	20.	m	Integrity and confidentiality of information		Click or tap here to enter text.
Recordkeeping							
☐	☐	☐	21.		Are complete records of receipt and distribution of drugs maintained?	**WAC 246-945-575** "Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. The records must include at least: (a) The source of the drugs, including the name and principal address of the seller or transferor; (b) The identity and quantity of the drugs received and distributed or disposed of; and (c) The dates of receipt and distribution or other disposition of the drugs."	Click or tap here to enter text.
☐	☐	☐	22.		Are records of suspicious orders and zero reports maintained and reported to the pharmacy commission in the appropriate time?	**WAC 246-945-585(1)** "Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission. (a) Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					identified as suspicious by the wholesaler, and must include, but not necessarily limited to: (i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."	
☐	☐	☐	23.	Are due diligence measures being followed to identify customers ordering or seeking to order controlled substances or drugs of concern?	**WAC 246-945-585(2)** Except as provided in subsection (3) of this section, a wholesaler shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary: (a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information; (b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished; (c) Review of drug utilization reports; and (d) Obtaining and conducting a review of the following: (i) Methods of payment accepted and in what ratios;	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales; (iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and (iv) The ratio of out-of-state patients served compared to in-state patients.	
☐	☐	☐	24.	If in an initial sale is conducted for an emergent need without performing the due diligence measures in WAC 246-945-585(2), are the provided criteria met?	**WAC 246-945-585(3)** A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (2) of this section if all of the following apply: (a) The sale is to a new customer; (b) The wholesaler documents that the order is to meet an emergent need; (c) The wholesaler completes the requirements of subsection (2) of this section no later than sixty business days from the date of sale.	Click or tap here to enter text.
☐	☐	☐	25.	Are existing customers providing explanation(s) when a request to purchase a controlled substance or drug of concern exceeds established limitations?	**WAC 246-945-585 (4)** A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.	Click or tap here to enter text.
☐	☐	☐	26.	Are records of potential diversion activity maintained and reported to the pharmacy commission in the appropriate time?	**WAC 246-945-585 (5)** Any customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell, shall be electronically reported to the commission. Such reports shall include: (a) Customer name; (b) Customer address; (c) DEA number; (d) State license number(s); (e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk; and (f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Controlled Substances						
☐	☐	☐	27.	Are complete records of controlled substance maintained?	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;	Click or tap here to enter text.
☐	☐	☐	28.	Are records of Schedule II drugs maintained separately from all other controlled substance records?	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records." **21 C.F.R 1304.04(h)** "Each registered pharmacy shall maintain the inventories and records of controlled substances as follows: (1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	29.	Does the wholesaler have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	30.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 C.F.R 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	31.	Is an inventory of controlled substances being performed every 2 years? An inventory of controlled substances must be completed within 30 days of a new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances.	**WAC 246 945 040(1)** "The commission adopts 21 CFR as its own. The following sections do not apply: Sec. 1301.13, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1303, Sec. 1308.41-.45, and Sec. 1316.31-.67. Any inconsistencies between 21 CFR Sec. 1300 through 1321 and this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board. **WAC 246-945-040(3)** Recordkeeping and Inventory. Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11. **21 CFR 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory." (b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. (d) Inventory date for newly controlled substances. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section. (e) Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors. Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below. (2) Inventories of distributors. Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.	
☐	☐	☐	32.	Does the wholesaler have power of attorney forms for ordering schedule II controlled substances?	**21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.
☐	☐	☐	33.	Has the wholesaler reported a loss of controlled substances in the previous 24 months to the DEA and the pharmacy commission?	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-9945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.

Read this Page Carefully

WA Pharmacy Quality Assurance Commission

~~2023~~2024 General Pharmacy Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

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

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

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

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

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

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

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

Washington State Department of Health

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

Date ~~responsible pharmacy manager~~ self-inspection worksheet was ~~performed~~completed: Click or tap to enter a date.

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

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

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

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

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

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

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

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

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

Yes	No	
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2023~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2023~~2024 Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Please answer the following three questions to identify additional required self-inspection forms.		
☐	☐	**Does the pharmacy fill prescriptions for residents of long-term care facilities or hospice programs? (This includes retail/community pharmacies and closed-door long-term care pharmacies, as defined in RCW 18.64.011(4).)** **If yes,** please complete the ~~2023~~2024 Long-Term Care Pharmacy Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Is the pharmacy licensed as a hospital pharmacy and/or have HPACs?** **If yes,** please complete the ~~2023~~2024 Hospital and HPAC Pharmacy Self-Inspection Addendum instead of the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy have an endorsement as a Nuclear Pharmacy?** **If yes,** please complete the ~~2023~~2024 Nuclear Pharmacy Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Document and Record Review

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

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

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

	Rule Reference
Collaborative Drug Therapy Agreement(s) (CDTA), if applicable Location: Click or tap here to enter text.	**WAC 246-945-350(1)** "A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location." A CDTA must include the elements listed WAC 246-945-350(2) and only valid for two years from the date of signing. (4) Any modification of the written guideline or protocol shall be treated as a new CDTA.
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	1.	Is the current pharmacy license posted?	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	2.	Are the pharmacist license(s) posted and up to date?	**RCW 18.64.140** "…The current license shall be conspicuously displayed to the public in the pharmacy to which it applies…"	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	3.	Does the pharmacy have a DEA registration number, is it listed on page 3 of this document?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	4.	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	**WAC 246-945-~~332~~310** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	5.	Are ancillary personnel certification(s) and registration(s) up to date? Please provide documentation of a regular staff roster with credential and expiration date.	**WAC 246-945-205(2)** "To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020," **WAC 246-945-200(1)** "To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of ~~chapter~~WAC 246-12~~ WAC, Part 2~~-020."	Click or tap here to enter text.
			6.	Pharmacy technician-in-training authority for experiential training.	**WAC 246-945-203(3)** "Before beginning the pharmacy-technician training program the individual shall submit an application to the commission to become certified as a pharmacy assistant. The application must include verification of enrollment in a commission-approved pharmacy-technician education and training program." (2) An individual with a technician in training endorsement may only work in that capacity at those sites identified on the application.	
Facility Standards						
☐	☐	☐	~~6.~~7.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access?	**WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	~~7.~~8.	Is the facility properly equipped?	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	~~8.~~9.	Is the facility appropriately staffed?	**WAC 246-945-410(3)** "The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation."	Click or tap here to enter text.
☐	☐	☐	~~9.~~10.	Is the facility adequately stocked?	**WAC 246-945-410(4)** "The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~10.~~11	Does the facility have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	~~11.~~12	Does each drug dispensed and delivered to patient bear a complete and accurate label?	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325."	Click or tap here to enter text.
☐	☐	☐	~~12.~~13	Are the drug storage areas appropriately secure from unauthorized access?	**WAC 246-945-410 (10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	~~13.~~14	Is a sign posted in view of patients informing them of generic substitution requirements?	**RCW 69.41.160** "Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, 'Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.'"	Click or tap here to enter text.
☐	☐	☐	~~14.~~15	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? **Electronic monitoring is acceptable.**	**WAC 246-945-415(1)**" A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
☐	☐	☐	~~15.~~16	Are freezers between -25° & -10°C (-13° & 14°F)?	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Ancillary Personnel						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~16.~~17	Is the pharmacy adhering to a commission approved Ancillary Utilization Plan?	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **WAC 246-945-410(11)** "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."	
☐	☐	☐	~~17.~~18	Are pharmacy assistants operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (2) 'Pharmacy assistants' may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt." **WAC 246-945-315(3**) "A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions."	Click or tap here to enter text.
☐	☐	☐	~~18.~~19	Are pharmacy technicians operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (1) "Pharmacy technicians" may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt... ." **WAC 246-945-315(2)** "When delegating a pharmacy function to a pharmacy technician: (a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and (b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320."	
Recordkeeping						
☐	☐	☐	~~19.~~20	An electronic recordkeeping system is required. Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	Click or tap here to enter text.
☐	☐	☐	~~20.~~21	~~Does all nonsterile and sterile compounding comply with USP Chapter <825>, if applicable?~~Do pharmacists review and document that refills for controlled substances in Schedules III and IV are correct?	~~**WAC 246-945-100** "Compounding minimum standards. **(1)** All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration.... (d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding,~~	~~Click or tap here to enter text.~~

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~Dispensing, and Repackaging."~~**RCW 69.50.306 and 21 CFR 1306.22 (f)(3)** "Refilling of prescriptions.(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown.	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~21.~~22	Do medications dispensed under ~~and~~an emergency proclamation meet all requirements?	**WAC 246-945-332** "Continuity of care (2) For each medication dispensed under this section, a pharmacist shall: (a) Document the dispensing as a prescription, noting where the information from subsection (1)(a) of this section was obtained; (b) Inform the patient's provider and the pharmacy at which the patient obtains his or her medications of the dispensing as soon as possible following the emergency dispensing; (c) Record the prescription or patient record as an "emergency" prescription."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~22.~~23	Is prescription adaptation in compliance with laws and rules ~~with regard to~~regarding quantity, dosage form, completion of missing information, and documentation in the patient's record?	**WAC 246-945-335** "Prescription adaptation. Upon patient consent, a pharmacist may adapt drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted. **(1)** Change quantity. A pharmacist may change the quantity of medication prescribed if: (a) The prescribed quantity or package size is not commercially available; (b) The change in quantity is related to a change in dosage form; (c) The change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520; or (d) The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program in accordance with RCW 48.43.096. **(2)** Change dosage form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. **(3)** Complete missing information. A pharmacist may complete missing information on a prescription if there is evidence to support the change. **(4)** Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record."	Click or tap here to enter text.
☐	☐	☐	~~23.~~24	Are all drug or biologic product substitutions in compliance with ~~the~~ applicable laws and rules?	**WAC 246-945-340** "Prescriptions—Drug product substitutions. **(1)** A pharmacist may substitute a drug or biologic product dispensed pursuant to a prescription if in compliance with applicable laws and rules. **(2)** A pharmacist may substitute a drug product or a biologic product when any of the following applies: (a) The substitution is permitted by RCW 69.41.120; (b) The substitution is permitted by a formulary developed by an interdisciplinary team of an institutional facility; or (c) The substitution is otherwise permitted by law." **(3)** In addition to any other applicable requirements, a pharmacist shall only substitute a drug or a biologic	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					product pursuant to subsection (2)(b) of this section if: (a) An employee or contractor of the institutional facility prescribed the drug or biologic product to be substituted; (b) The interdisciplinary team was composed of a nonpharmacist prescriber listed in RCW 69.41.030 and a pharmacist; and (c) The formulary is readily retrievable by the pharmacist."	
☐	☐	☐	~~24.~~25	Are lawfully prescribed drugs and devices or a therapeutically equivalent drug or device delivered to patients in a timely manner?	**WAC 246-945-415** "Dispensing and delivery of prescription drugs **(2)** Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances: (a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-945-410(8) or 246-945-335; (b) National or state emergencies or guidelines affecting availability, usage, or supplies of drugs or devices; (c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine; (d) Potentially fraudulent prescriptions; or (e) Unavailability of drug or device despite good faith compliance with WAC 246-945-410(4). **WAC 246-945-415 (3)** Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge."	Click or tap here to enter text.
☐	☐	☐	~~25.~~26	Does the pharmacy provide the patient or agent with a timely alternative, if the lawfully prescribed drug is not in stock, or the prescription cannot be filled?	**WAC 246-945-415 (4)** "If despite good faith compliance with WAC 246-945-410(4), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (2)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					pharmacy practice, may include obtaining the drug or device. These alternatives include, but are not limited to: (a) Contact the prescriber to address concerns such as those identified in subsection (2)(a) of this section or to obtain authorization to provide a therapeutically equivalent product; (b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or (c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner." **WAC 246-945-415 (5)** "Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions: (a) Destroy unfilled lawful prescriptions; (b) Refuse to return unfilled lawful prescriptions; (c) Violate a patient's privacy; (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and (e) Intimidate or harass a patient."	
☐	☐	☐	~~26.~~27	~~Does the~~If your pharmacy ~~have~~utilizes a ~~secured~~secure delivery area ~~equipped with~~, does the area have adequate security and ~~is this addressed in the pharmacy's policy~~policies and procedures relating to the delivery area?	**WAC 246-945-415 (6)** "Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the drug storage area. The secured delivery area must be a part of a licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager."	Click or tap here to enter text.
☐	☐	☐	~~27.~~28	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR, Part 1700, unless: (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant. (b) Authorization is obtained from the patient or a representative of the	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
				** Best practice recommendation: It is recommended that these authorizations are updated annually. **		patient to dispense in a container that is not child-resistant."	
			~~28.~~29	Do all prescriptions for non-controlled legend drugs ~~have~~include all required elements?		**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500."	
☐	☐	☐	28.	a	Prescriber's Name		Click or tap here to enter text.
☐	☐	☐	28.	b	Name of Patient/ Authorized entity/Animal Name and Species		Click or tap here to enter text.
☐	☐	☐	28.	c	Date of Issuance		Click or tap here to enter text.
☐	☐	☐	28.	d	Drug Name, Strength, and quantity		Click or tap here to enter text.
☐	☐	☐	28.	e	Directions for Use		Click or tap here to enter text.
☐	☐	☐	28.	f	Number of Refills		Click or tap here to enter text.
☐	☐	☐	28.	g	Substitution Directions		Click or tap here to enter text.
☐	☐	☐	28.	h	Prescribers Signature		Click or tap here to enter text.
☐	☐	☐	28.	i	If written, on Tamper-resistant Paper		Click or tap here to enter text.
			~~29.~~30	Do all prescriptions for controlled drugs ~~have all~~include additional ~~of the~~ required elements?		**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 CFR, Chapter II."	
☐	☐	☐	29.	a	Patient's address		Click or tap here to enter text.
☐	☐	☐	29.	b	Dosage Form		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	29.	c	~~Prescriber'~~Prescriber's address		Click or tap here to enter text.
☐	☐	☐	29.	d	Prescriber's DEA number		Click or tap here to enter text.
☐	☐	☐	~~30.~~31		~~Does the~~Do chart ~~order~~orders meet requirements?	**WAC 246-945-010 (5)** "A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II"	Click or tap here to enter text.
☐	☐	☐	~~31.~~32		Do ~~all~~ emergency prescriptions for Schedule II controlled substances meet ~~the~~ requirements?	**WAC 246-945-010 (6)** "A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency." (a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time. (b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.	Click or tap here to enter text.
☐	☐	☐	~~32.~~33		Are all ~~emergency~~ controlled substances prescribed orally reduced to a written or electronic prescription?	**WAC 246-945-010 (7)** "A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.
☐	☐	☐	~~33.~~34		Are all ~~uncontrolled~~noncontrolled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	**WAC 246-945-010 (8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~34.~~35	Are all drugs dispensed pursuant to valid prescriptions?	**WAC 246-945-011** "Prescription validity. **(1)** Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity. **(2)** A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075]	Click or tap here to enter text.
☐	☐	☐	~~35.~~36	Do all paper prescriptions contain two lines clearly identified for a practitioner's signature, one that denotes "dispense as written" and the other "substitution permitted"? This is not necessary if substitution is permitted by a prior consent authorization.	**RCW 69.41.120 (1)** "Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization. If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	
☐ ☐	☐ ☐	☐ ☐	~~36.~~37	Are paper prescriptions for controlled substances maintained ~~in appropriate files?~~appropriately?	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."	Click or tap here to enter text.
☐	☐	☐	~~37.~~38	Are ~~electronic~~paper prescriptions for noncontrolled substances maintained appropriately?	~~**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311."~~**RCW 69.41.120(4) "**The pharmacist shall retain the file copy of a written or oral prescription for the same period of time specified in RCW 18.64.245 for retention of prescription records."	~~Click or tap here to enter text.~~
☐ ☐	☐ ☐	☐ ☐	~~38.~~39	Are electronic prescriptions maintained appropriately?~~Do the prescription records contain a complete auditable trail?~~	**WAC 246-945-417(~~2~~)** ~~"The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the~~ **~~6)~~** "Electronic prescriptions for prescription ~~where possible~~drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~39.~~40	Do the prescription records contain a complete auditable trail?~~Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?~~	**WAC 246-945-417** ~~"Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records.~~ **~~(3)~~** **(2)** "The electronic recordkeeping system must ~~include security features to protect the confidentiality and integrity~~be capable of ~~patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation~~real-time retrieval of ~~prescription~~ information ~~and patient medication records; and (b) Functionality that documents any alteration~~pertaining to the ordering, verification, and processing of ~~prescription information after a prescription is dispensed, including~~ the ~~identification of the individual~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~responsible for the alteration.~~prescription where possible."	
☐ ☐	☐ ☐	☐ ☐	~~40.~~41	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?~~Do non-controlled substance prescription transfers contain sufficient information and maintain an auditable trail?~~ ~~*See 21 CFR 1306.25 (b) for the requirements for transferring controlled substance prescriptions.~~	**WAC 246-945-~~345~~** "Prescription transfers. … ~~(2)~~ Upon **417** "Electronic systems for patient ~~request, a prescription may be transferred within the limits of state and federal law."~~medication records, prescriptions, chart orders, and controlled substance records. ~~(3) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription."~~ ~~(4) Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing."~~ ~~(5) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations."~~**(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~41.~~42	Do non-controlled substance prescription transfers contain sufficient information and maintain an auditable trail? *See 21 CFR 1306.08(e-f) and 21 CFR 1306.25 (b) for the requirements for transferring controlled substance prescriptions.~~Do prescription records properly document partial fills?~~	**WAC 246-945-~~013~~** "Partial filling of prescriptions. **345** "Prescription transfers. … ~~(1)~~ A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that: (a) The partial fill is requested by the patient or the prescriber; (b) The partial filling is recorded in the same manner as a re-filling; (c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and (d) Partial fills for controlled substances listed in Schedule III through V comply with 21 CFR Sec. 1306.23. ~~(2)~~ A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.~~**(2)** Upon patient request, a prescription may be transferred within the limits of state and federal law." **(3)** Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription." **(4)** Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing." **(5)** Prescriptions must be transferred by electronic means or facsimile, except in emergent situations."	
☐ ~~☐~~ ☐	☐ ~~☐~~ ☐	☐ ~~☐~~ ☐	~~42.~~43	Do prescription records properly document partial fills?~~Does your pharmacy have shared pharmacy services or utilize a central fill?~~	**WAC 246-945-~~425~~013** "~~Pharmacy services~~ Partial filling of prescriptions. **(1)** A pharmacist may ~~be provided off-site at one or more locations. When the services being performed are related to~~partially fill a prescription ~~fulfillment or processing,~~ for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that: (a) The partial fill is requested by the patient or the ~~pharmacy or pharmacist~~ prescriber; (b) The partial filling is recorded in the same manner as a re-filling; (c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and (d) Partial fills for controlled substances listed in Schedule III through V comply with ~~the following: …~~ 21 CFR Sec. 1306.23. ~~**(2)** Central fill shared pharmacy services in accordance with the following conditions: (a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party; (b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and (c) A single prescription may be shared by an originating pharmacy and a central fill~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution."~~**(2)** A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.	
☐	☐	☐	~~43.~~44	~~Is an inventory of controlled substances conducted and maintained onsite at a minimum every two years?~~ If your pharmacy utilizes shared pharmacy services or central fill services, are there policies and procedures outlining these services?	~~**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years."~~ ~~-~~**WAC 246-945-425** "Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following: … **(2)** Central fill shared pharmacy services in accordance with the following conditions: (a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party; (b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and (c) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution."	Click or tap here to enter text.
☐	☐	☐	~~44.~~45	Is an inventory of controlled substances ~~completed within 30 days of~~conducted and maintained onsite	**WAC 246-945-420(~~3~~2)** "A facility shall conduct ~~its own separate~~an inventory of controlled substances ~~in the following situations: (a) Within thirty days of designating a~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				at a ~~new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances~~minimum every two years?	~~responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance~~every two years." This inventory~~. (b) On the effective date of an addition of a substance to a schedule of~~ shall include all controlled substances~~. Each facility that possesses the substance shall take an inventory of the substance~~ "on hand~~, and thereafter, include the substance in each inventory.""~~". ~~See also 21 CFR 1304.~~ 21 CFR 1304.11(a) "Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced…" This includes medications in will call.	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~45.~~46	~~If legend drugs (including~~Is an inventory of controlled substances~~) are dispensed~~ completed within 30 days of a new responsible manager or ~~delivered without a pharmacist on-site, is there~~ the effective date of the addition of a ~~perpetual inventory~~substance to a schedule of controlled substances?	~~**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory."~~**WAC 246-945-420(3)** "A facility shall conduct its own separate inventory of controlled substances in the following situations: (a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~46.~~47	If ~~prescription~~legend drugs (including controlled substances) are dispensed or delivered without ~~pharmacy ancillary personnel physically~~a pharmacist on-site, is there a perpetual inventory?	**WAC 246-945-420(~~54~~)** "A pharmacy that exclusively stores, dispenses or delivers ~~prescription~~legend drugs, including controlled substances, without ~~pharmacy ancillary personnel physically~~a pharmacist on-site shall maintain a perpetual inventory."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~47.~~48	If prescription drugs are dispensed or delivered without pharmacy ancillary personnel physically on-site, is there	~~**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				a perpetual inventory?~~Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?~~	~~required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."~~ **~~WAC 246-945-001(71)~~** ~~""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."~~**WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~48.~~49	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?~~Does the pharmacy maintain records of all receipt and distribution of controlled substances?~~	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." ~~**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; … (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.~~**WAC 246-945-001(71)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	
☐ ☐	☐ ☐	☐ ☐	~~49.~~50	~~Are~~Does the pharmacy maintain records of ~~Schedule II drugs maintained separately from~~ all ~~other~~receipt and distribution of controlled ~~substance records~~substances?	**~~WAC 246-945-040(4)~~** ~~"Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."~~**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; … (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~50.~~51	Are records of Schedule ~~III-V~~II drugs maintained ~~either~~ separately ~~or in a form that is readily retrievable~~ from all other controlled substance records?	**WAC 246-945-040(~~5~~4)** "Credential holders and pharmaceutical firms ~~may~~shall maintain records for Schedule ~~III, IV, and V~~II drugs ~~either~~ separately ~~or in a form that is readily retrievable~~ from ~~the business~~all other records ~~of the registrant~~."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~51.~~52	~~Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution~~Are records of Schedule ~~I~~III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(~~6~~5)** ~~"A federal order form is required for each distribution of a Schedule I or II controlled substance.~~ "Credential holders and pharmaceutical firms ~~must keep and make readily available these forms and other~~may maintain records ~~to~~for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the ~~commission or its designee~~business records of the registrant."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~52.~~53	Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution of	**WAC 246-945-040(~~3~~)(~~c~~)** ~~"In the event~~**6)** "A federal order form is required for each distribution of a ~~significant loss~~Schedule I or ~~theft, two copies of DEA 106 (report of~~	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
					Schedule II drugs?~~Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, and other appropriate authorities?~~	~~theft or loss of~~II controlled ~~substances)~~substance. Credential holders and pharmaceutical firms must ~~be transmitted to the federal authorities and a copy must be sent~~keep and make readily available these forms and other records to the commission or its designee."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~53.~~54		Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, and other appropriate authorities?~~Are all records maintained for a minimum of two years or for a time period otherwise required?~~ ~~For example, if a Pharmacy is storing, dispensing, and delivering medications without a pharmacist on-site, it must have adequate visual surveillance of the full pharmacy and retain a high-quality recording for a minimum of thirty calendar days.~~	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission."~~**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."~~	Click or tap here to enter text.
Professional Requirements							
Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets and binders).							
			~~54.~~55		Does the pharmacy have policies and procedures in place for the following as applicable?	**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	a	Purchasing Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	b	Ordering Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	c	Storing Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	d	Compounding Location or file pathway:		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	54.	e	Delivering Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	54.	f	Dispensing Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	54.	g	Administration Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	~~55.~~56		Does the pharmacy have a policy in place if a computer system downtime occurs? Location or file pathway:	**WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.
☐	☐	☐	~~56.~~57		Do pharmacists perform drug utilization reviews when required?	**WAC 246-945-001(29)** "'Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: (a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~57.~~58	Do pharmacists perform patient counseling?	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~58.~~59	~~Do~~ Are pharmacists ~~that engage in activities~~practicing under a valid and unexpired collaborative drug therapy agreement (CDTA~~) have an unexpired CDTA containing the minimum required elements?~~)?	**WAC 246-945-350 "**Collaborative drug therapy agreements. **(1)** A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location. **(2)** A CDTA must include: (a) A statement identifying the practitioner authorized to prescribe and the name of each pharmacist who is party to the agreement; (i) The practitioner authorized to prescribe must be in active practice; and (ii) The authority granted must be within the scope of the practitioners' current practice. (b) A statement of the type of prescriptive authority decisions which the pharmacist is authorized to make, which includes: (i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case. (ii) A general statement of the training required, procedures, decision criteria, or plan the pharmacist is to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved. (c) A statement of the activities the pharmacist is to follow in the course of exercising prescriptive authority, including: (i) Documentation of decisions made; and (ii) A plan for communication or feedback to the authorizing practitioner concerning specific decisions made. **(3)** A CDTA is only valid for two years from the date of signing.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(4) Any modification of the written guideline or protocol shall be treated as a new CDTA."	
☐	☐	☐	~~59.~~60	Is all merchandise in date? Including OTC medications anywhere within the store, not solely behind the counter. *It's advised to perform an inventory check for expired medications while filling out this self- inspection report*	**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
☐	☐	☐	~~60.~~61	Does the pharmacy meet the requirements for the return and reuse of medications?	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	Click or tap here to enter text.
☐	☐	☐	~~61.~~62	Does the pharmacy meet the requirements for return and destruction of medications?	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures	Click or tap here to enter text.
☐	☐	☐	~~62.~~63	Does the pharmacy of a licensed hospital or health care entity possess, distribute, or dispense legend drug samples? Note: Other pharmacies not listed above should mark N/A.	**WAC 246-945-035** "Drug sample prohibitions **(1)** "Except as provided in subsection (2) of this section, a pharmacy shall not possess, distribute or dispense legend drug samples. **(2)** A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples."	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~63.~~64	Are all drugs ready to be dispensed to patients properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?	**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "Prescriptions—Outpatient labels—Minimum requirements. **(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors."	
☐	☐	☐	~~64.~~65	Does the pharmacy have required policies and procedures for drugs stored outside of the pharmacy?	**WAC 246-945-455(1)** "In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met: (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; (b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450; (d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs."	Click or tap here to enter text.
☐	☐	☐	~~65.~~66	Are prescriptions being refilled in accordance with pharmacy laws and rules?	**WAC 246-945-012** "Prescription refills. **(1)** A prescription for a controlled substance listed in Schedule II cannot be refilled. **(2)** A prescription for a controlled substance listed in Schedule III, IV, or V may be refilled a maximum of five times as indicated by the prescriber. The prescription will expire six months after the date of issue pursuant to WAC 246-945-011 even if there are refills remaining. **(3)** A prescription for a noncontrolled legend drug may be refilled as indicated by the prescriber in accordance with	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					RCW 18.64.520. There is no limit on the number of refills, but the prescription will expire after twelve months from the date of issue pursuant to WAC 246-945-011." **WAC 246-945-330** "Refilling prescriptions. **(1)** A prescription may be refilled when permitted by state and federal law and only as authorized by the prescriber. **(2)** Except as provided in subsection (1) of this section, a pharmacist may renew a prescription for a noncontrolled legend drug one time in a six-month period when an effort has been made to contact the prescriber and they are not available for authorization under the following conditions: (a) The amount dispensed is the quantity on the most recent fill or a thirty-day supply, whichever is less; (b) The refill is requested by the patient or the patients agent; (c) The patient has a chronic medical condition; (d) No changes have been made to the prescription; and (e) The pharmacist communicates the renewal to the prescriber within one business day."	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~66.~~67	When prescriptions are delivered, does the pharmacy have appropriate measures in place to ensure product integrity?	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
Remote Supervision and Access in the Absence of a Pharmacist						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~67.~~68	Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site? **If you answered "~~No~~N/A" to question 67, mark questions 68-~~74~~7 N/A.	**WAC 246-945-430(1)** "The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~68.~~69	Does the pharmacy have full visual surveillance of the pharmacy?	**WAC 246-945-430(2)** "The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high quality recording for a minimum of thirty calendar days."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~69.~~70	Is access to the pharmacy limited and monitored?	**WAC 246-945-430(3)** "Access to a pharmacy by individuals must be limited, authorized, and regularly monitored."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~70.~~71	Does the monitoring system include visual and audio communication?	**WAC 246-945-430(4)** "A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant."	Click or tap here to enter text.
☐	☐	☐	~~71.~~72	Does the responsible pharmacy manager or designee perform monthly in-person inspections of the pharmacy?	**WAC 246-945-430(5)** "The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	~~72.~~73	Can a pharmacist be on-site within 3 hours of an emergency?	**WAC 246-945-430(6)** "A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises."	Click or tap here to enter text.
☐	☐	☐	~~73.~~74	Does the pharmacy close in the event of a surveillance system failure?	**WAC 246-945-430(7)** "The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations."	Click or tap here to enter text.
☐	☐	☐	~~74.~~75	Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?	**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory." **WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	Click or tap here to enter text.

Washington State Department of Health

Read this Page Carefully

Pharmacy Quality Assurance Commission

~~2023~~2024 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005~~)~~(4)) may result in disciplinary action.

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

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

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

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

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

Health Care Entity (HCE) Self-Inspection Worksheet

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

Date ~~responsible pharmacy manager~~ self-inspection worksheet was ~~performed~~complete: Click or tap to enter a date.

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

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

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

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

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

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

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

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

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

Yes	No	
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	Do ~~pharmacy~~HCE personnel engage in non-sterile compounding of medications? **If yes, please complete the ~~2021~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.**
☐	☐	Do ~~pharmacy~~HCE personnel engage in sterile compounding? **If yes, you must also complete the ~~2021~~2024 Sterile Compounding Self-Inspection Addendum. If compounding falls under the 'immediate use exemption' as interpreted by the commission *and* is in the retail/community pharmacy setting then the sterile compounding self-inspection worksheet does not need to be completed.**

Document and Record Review

Please provide the location of these documents in the facility (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below ~~are~~is required by rule ~~references to~~and must be ~~available~~readily retrievable during inspection~~, by~~. By listing the location of these documents, you are also confirming ~~your~~ compliance with the referenced rule.

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

	Rule Reference
	shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR. 1305.13(e**) "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR. 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR. 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR. as its own." **21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."
Prescription Records for the last 2 years	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: **(a)** Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions.

	Rule Reference
Location: Click or tap here to enter text.	**(b)** Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

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

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				prescription preparation, and product integrity?	the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
☐	☐	☐	6.	Does the facility have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: **(a)** By the date of opening; and **(b)** Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	7.	Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?	**WAC 246-945-410(10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: **(a)** A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or **(b)** A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or **(c)** The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	8.	Are medication refrigerator temperatures maintained between 2- 8°C (36-46°F)? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	9.	Are medication freezer temperatures maintained between -25°& -10°C (-13° & 14°F) or within acceptable range based on product packaging? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	10.	Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label? **Including samples under the control of the HCE**	**RCW 69.45.040(3)** "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. **(4)** Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
☐	☐	☐	11.			**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **RCW 69.45.040(5)** "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
				Is all drug stock in date? **Including OTC medications and samples under the control of the HCE** *It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.*			

Policies and Procedures

Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets).

			12.	Does the HCE have policies and procedures in place for the following:		**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
☐	☐	☐	12.	a	Purchasing		Click or tap here to enter text.
☐	☐	☐	12.	b	Ordering		Click or tap here to enter text.
☐	☐	☐	12.	c	Storing		Click or tap here to enter text.
☐	☐	☐	12.	d	Compounding		Click or tap here to enter text.
☐	☐	☐	12.	e	Delivering		Click or tap here to enter text.
☐	☐	☐	12.	f	Dispensing		Click or tap here to enter text.
☐	☐	☐	12.	g	Administration		Click or tap here to enter text.

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

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

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

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

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

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

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Dispensing – HCEs that do not dispense for use outside the HCE and answer "No" to question 31 may skip question numbers 32-~~47~~41						
☐	☐	☐	31.	Does the HCE dispense prescription medications to patients for at home use?	**RCW 18.64.450(4)** "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	Click or tap here to enter text.
☐	☐	☐	32.	If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?	**RCW 18.64.450(4)** "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage."	Click or tap here to enter text.
☐	☐	☐	33.	Does the HCE have valid prescription records for all drugs dispensed to patients?	**WAC 246-945-410(7)** "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." **WAC 246-945-011(1)** "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." **(2)** A prescription shall be considered invalid if: **(a)** At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; **(b)** The prescription does not contain the required information as provided in WAC 246-945-010; **(c)** The prescription is expired; or **(d)** The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: **(a)** The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. **(b)** The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	Click or tap here to enter text.
☐	☐	☐	34.	Are all non-controlled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	**WAC 246-945-010(8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.

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

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

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

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

Read this Page Carefully

WA Pharmacy Quality Assurance Commission
~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

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

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

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

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

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

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

Questions highlighted in **blue** are ~~questions that will be focused on~~common areas of non-compliance observed during routine pharmacy inspections.

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

Washington State Department of Health

~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

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

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

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

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

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

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

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

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

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

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

Yes	No	
☐	☐	Are you a hospital pharmacy? **If yes, you must *only* complete the ~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet, unless you answer yes to any of the following.**
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2023~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.

☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2023~~2024 Sterile Compounding Self-Inspection Addendum in addition to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.
☐	☐	Do you have an endorsement as a Nuclear Pharmacy? **If yes, you must also complete the ~~2023 Nuclear~~2024 Radiopharmaceuticals Pharmacy Self-Inspection Addendum.**

Document and Record Review

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

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

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

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

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

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

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

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

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	21.	Do you have a policy addressing system downtime?	**WAC 246-945-417(4)** The pharmacy shall have policies and procedures in place for system downtime.	Click or tap here to enter text.
☐	☐	☐	22.	If providing central fill services, does the pharmacy have policies and procedures outlining off-site pharmacy services?	**WAC 246-945-425(2)(a)** The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party;	Click or tap here to enter text.
☐	☐	☐	23.	Does the pharmacy have policies and procedures for providing emergency discharge medications to patients?	**WAC 246-945-435(1)** The responsible pharmacy manager of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available. (2) The policies and procedures in subsection (1) of this section shall: (a) Comply with all requirements of RCW 70.41.480; (b) Ensure all prepackaged medications are affixed with a label that complies with WAC 246-945-018; (c) Require oral or electronically transmitted chart orders be verified by the practitioner in writing within seventy-two hours; (d) The medications distributed as discharge medications are stored in compliance with the laws concerning security and access; and (e) Ensure discharge medications are labeled appropriately. **RCW 70.41.480(2)(b)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW."	Click or tap here to enter text.
☐	☐	☐	24.	Does the pharmacy have policies and procedures for the use of patient own medications?	**WAC 246-945-440** Facilities shall develop written policies and procedures for the administration of patient owned medications.	Click or tap here to enter text.
☐	☐	☐	25.	Does the pharmacy have policies and procedures for nursing student administration of medications?	**WAC 246-945-450 (1)** Nursing students may be given access privileges to technology used to dispense medications for patient administration as provided for in this section. **WAC 246-945-450 (2)** Nursing students must be enrolled in a nursing program approved by the Washington state nursing care quality assurance commission in accordance with WAC 246-840-510.	Click or tap here to enter text.

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

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

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	32.	Are all drug stock and devices in date and fit for use?	**RCW 69.04.100** Whenever the Pharmacy Quality Assurance commission shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use. **WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
Controlled Substance Accountability						
☐	☐	☐	33.	Are procedures established for effective accountability of controlled substances?	**WAC 246-945-040(1)** The commission adopts 21 CFR as its own. **21 CFR 1301.71** All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.	Click or tap here to enter text.
☐	☐	☐	34.	Does the pharmacy have a biennial controlled substance inventory completed within the last 2 years?	**21 CFR 1304.11** Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. **WAC 246-945-420(2)** A facility shall conduct an inventory of controlled substances every two years.	Click or tap here to enter text.
☐	☐	☐	35.	Does the pharmacy maintain records of all receipt and distribution of controlled substances?	**WAC 246-945-040(3)** Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	Click or tap here to enter text.

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

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

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

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

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

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	8.	b	Directions for use	pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. This section shall not apply to the dispensing of medications to in-patients in hospitals. **RCW 69.41.050(1)** To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient. **WAC 246-945-016** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	Click or tap here to enter text.
☐	☐	☐	8.	c	Brand or Generic Drug name and strength per dose		Click or tap here to enter text.
☐	☐	☐	8.	d	Name of patient, and		Click or tap here to enter text.
☐	☐	☐	8.	e	Date		Click or tap here to enter text.
Records							
			9.	For *automated* patient record systems: Do patient records include all required information?		**WAC 246-945-417(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. (3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and	
☐	☐	☐	9.	a	Patient full name and address		Click or tap here to enter text.
☐	☐	☐	9.	b	Serial number assigned to each new prescription		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	9.	c	Date of all instances of dispensing a drug	(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. (4) The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual record-keeping system be maintained. (5) The pharmacy shall maintain records in accordance with WAC 246-945-020. (6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311. (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
☐	☐	☐	9.	d	The identification of the dispenser who filled the prescription		Click or tap here to enter text.
☐	☐	☐	9.	e	Name, strength, dosage form, and quantity of drug dispensed		Click or tap here to enter text.
☐	☐	☐	9.	f	Prescriber's name address, and DEA number where required.		Click or tap here to enter text.
☐	☐	☐	9.	g	Any refill instructions by the prescriber		Click or tap here to enter text.
☐	☐	☐	9.	h	Complete directions for use of the drug, which prohibits use of "as directed"		Click or tap here to enter text.
☐	☐	☐	9.	i	Authorization for other than child-resistant containers, if applicable.		Click or tap here to enter text.
☐	☐	☐	10.		Are allergies and chronic conditions identified in patient records?	**WAC 246-945-417(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. **WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	Click or tap here to enter text.
			11.		For *manual* patient record systems: Do patient records include all required information?	**WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The	

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	11.	a	Patient full name and address	record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	Click or tap here to enter text.
☐	☐	☐	11.	b	Serial number assigned to each new prescription		Click or tap here to enter text.
☐	☐	☐	11.	c	Date of all instances of dispensing a drug		Click or tap here to enter text.
☐	☐	☐	11.	d	The identification of the dispenser who filled the prescription		Click or tap here to enter text.
☐	☐	☐	11.	e	Name, strength, dosage form, and quantity of drug dispensed		Click or tap here to enter text.
☐	☐	☐	11.	f	Prescriber's name address, and DEA number where required.		Click or tap here to enter text.
Drug Administration							
☐	☐	☐	12.		Is access to the drug storage area of the HPAC limited only to those WA credentialed personnel acting within their scope of practice? *Nursing students acting within their scope of practice can administer medications.*	**WAC 246-945-455(1)(c)** Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450. **WAC 246-945-317 Tech check tech. (1)** "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example. (2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	13.	Are all drugs in an HPAC dispensed only upon a valid order or a practitioner?	**WAC 246-945-410(7)** Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. **WAC 246-945-011(5)** A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. **RCW 18.64.550(1)** A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature.	Click or tap here to enter text.

6.1. 2024 PQAC Master Calendar Approval

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
Date	**Time**	**Activity**	**Who**	**Location**
January 3, 2024	12:00-1:30 pm	CMT	Panel A	Teams
Janaury 5, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 10, 2024	12:00-1:30 pm	CMT	Panel B	Teams
January 12, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 17, 2024	12:00-1:30 pm	CMT	Panel C	Teams
January 19, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 24, 2024	12:00-1:30 pm	CMT	Panel A	Teams
January 24, 2024	TBD	Legislative Day	WSPA	TBD
January 26, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 1, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 2, 2024	8:00-9:00 am	CMT	Panel B	TBD and Teams
February 2, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 7, 2024	12:00-1:30 pm	CMT	Panel C	Teams
February 9, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
Feburary 11-13, 2024	TBD	Nt'l Assoc. of Chain Drug Stores Regional Meeting	PQAC	Bonita Springs, FL
February 14, 2024	12:00-1:30 pm	CMT	Panel A	Teams
February 16, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
Feburary 19, 2024	TBD	Legislative Day - Community	WSPA	TBD
February 21, 2024	12:00-1:30 pm	CMT	Panel B	Teams
February 23, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 28, 2024	12:00-1:30 pm	CMT	Panel C	Teams
March 1, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 7, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 8, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
March 8, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 13, 2024	12:00-1:30 pm	CMT	Panel B	Teams
March 15, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 20, 2024	12:00-1:30 pm	CMT	Panel C	Teams
March 27, 2024	12:00-1:30 pm	CMT	Panel A	Teams
April 3, 2024	12:00-1:30 pm	CMT	Panel B	Teams
April 10, 2024	12:00-1:30 pm	CMT	Panel C	Teams
April 16-19, 2024	TBD	Academy of Managed Care Pharmacy's Nt'l Meeting	PQAC	New Orleans, LA
April 17, 2024	12:00-1:30 pm	CMT	Panel A	Teams
April 24, 2024	12:00-1:30 pm	CMT	Panel B	Teams
April 27-30, 2024	TBD	Nt'l Assoc. of Chain Drug Stores' Annual Meeting	PQAC	Palm Beach, FL
May 2, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
May 3, 2024	8:00-9:00 am	CMT	Panel C	Teams
May 3, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
May 8, 2024	12:00-1:30 pm	CMT	Panel A	Teams
May 15, 2024	12:00-1:30 pm	CMT	Panel B	Teams

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
May 15-17, 2024	TBD	Nt'l Assoc. of Boards of Pharmacy's 120th Annual Meeting	PQAC	Fort Worth, TX
May 22, 2024	12:00-1:30 pm	CMT	Panel C	Teams
May 29, 2024	12:00-1:30 pm	CMT	Panel A	Teams
May 30-June 2, 2024	TBD	WSPA's Northwest Pharmacy Convention	PQAC	Coeur D'Alene, ID
June 5, 2024	12:00-1:30 pm	CMT	Panel B	Teams
June 12, 2024	12:00-1:30 pm	CMT	Panel C	Teams
June 19, 2024	12:00-1:30 pm	CMT	Panel A	Teams
June 27, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
June 28, 2024	8:00-9:00 am	CMT	Panel B	TBD and Teams
June 28, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
July 3, 2024	12:00-1:30 pm	CMT	Panel C	Teams
July 10, 2024	12:00-1:30 pm	CMT	Panel A	Teams
July 24, 2024	12:00-1:30 pm	CMT	Panel B	Teams
July 31, 2024	12:00-1:30 pm	CMT	Panel C	Teams
August 7, 2024	12:00-1:30 pm	CMT	Panel A	Teams
August 14, 2024	12:00-1:30 pm	CMT	Panel B	Teams
August 22, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
August 23, 2024	8:00-9:00 am	CMT	Panel C	TBD and Teams
August 23, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
August 28, 2024	12:00-1:30 pm	CMT	Panel A	Teams
September 4, 2024	12:00-1:30 pm	CMT	Panel B	Teams
September 11, 2024	12:00-1:30 pm	CMT	Panel C	Teams
September 18, 2024	12:00-1:30 pm	CMT	Panel A	Teams
September 25, 2024	12:00-1:30 pm	CMT	Panel B	Teams
October 2, 2024	12:00-1:30 pm	CMT	Panel C	Teams
October 7-8, 2024	TBD	American Society of Health Systems Pharmacists (ASHP)'s Conference for Pharmacy Leaders	PQAC	Chicago, IL
October 10, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
October 11, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
October 11, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
October 16, 2024	12:00-1:30 pm	CMT	Panel B	Teams
October 20-23, 2024	TBD	AMCP Nexus 2024	PQAC	Las Vegas, NV
October 20-24, 2024	TBD	National Association of Boards of Pharmacy District 6, 7, & 8 Meeting	PQAC	Albequerque, NM
October 23, 2024	12:00-1:30 pm	CMT	Panel C	Teams
October 30, 2024	12:00-1:30 pm	CMT	Panel A	Teams
November 6, 2024	12:00-1:30 pm	CMT	Panel B	Teams
November 7, 2024	TBD	2024 ASCP Annual Meeting and Exhibition	PQAC	Aurora, CO
November 13, 2024	12:00-1:30 pm	CMT	Panel C	Teams
November 20, 2024	12:00-1:30 pm	CMT	Panel A	Teams
November 27, 2024	12:00-1:30 pm	CMT	Panel B	Teams
December 4, 2024	12:00-1:30 pm	CMT	Panel C	Teams
December 8-12, 2024	TBD	ASHSP's Midyear Clinical	PQAC	New Orleans, LA

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
December 12, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
December 13, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
December 13, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
December 18, 2024	12:00-1:30 pm	CMT	Panel B	Teams
December 25, 2024	Cancelled (holiday)	CMT	Panel C	Teams

WAC 246-945-345 Prescription transfers. (1) Subsections (2) through (~~5~~6) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.08 and Sec. 1306.25.

(2) Upon request by a patient or authorized representative of a patient ~~request~~, a prescription ~~may~~ shall be transferred within the limits of state and federal law.

(3) Facilities shall fulfill prescription transfer requests at the time of request to the transferred individual's or individual's authorized representative's requested facility.

(~~3~~4) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription.

(~~4~~5) Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing.

(~~5~~6) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470,

18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-345, filed 6/1/20, effective 7/1/20.]

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: December 08, 2023
TIME: 8:42 AM

WSR 24-01-021

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: Naloxone nasal spray as over-the-counter status**.** In March 2023, the United States Food and Drug Administration (FDA) approved the first 4 mg naloxone hydrochloride nasal spray as an over-the-counter (OTC) drug and has approved other naloxone nasal sprays since that time. Naloxone is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose. Currently, WAC 246-945-030 incorporates the 39th edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, or "Orange Book," which has naloxone listed as a prescription drug. The Pharmacy Quality Assurance Commission (commission) considers the ongoing opioid epidemic to be a public health emergency in Washington state. In order to combat this epidemic in Washington, the commission is amending WAC 246-945-030 and adding a new section, WAC 246-945-034, classifying the 3mg and 4mg naloxone hydrochoride nasal spray as approved by the FDA for OTC distribution as an OTC drug in Washington state.

The timeline for the availability of naloxone nasal spray is set by the manufacturers, although some are already available. This emergency rule prepares Washington state for the moment that the drug becomes available by manufacturers. The proposed new section of chapter 246-945 WAC would also allow for expansion of different formularies if the FDA makes further changes. This preparation would allow for a faster release of the drug throughout the state, meaning this life saving drug would be in the hands of Washingtonians faster. Increasing patient access to the drug is critical to reduce opioid overdoses.

This emergency rule filing allows for the 3mg and 4mg dosage versions of naloxone spray to be prescribed as over-the-counter products. The previous emergency rule filing on this topic, filed as WSR 23-17-059 on August 11, 2023, only allowed the 4 mg nasal spray under the brand name Narcan to be prescribed as an OTC product, but the FDA broadened the classification of allowed naloxone products since that previous filing.

Citation of rules affected by this order:

New: WAC 246-945-034
Repealed: None
Amended: WAC 246-945-030
Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

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

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

Reasons for this finding: The immediate adoption of this rule is necessary for the preservation of public health, safety, and general welfare. The opioid epidemic is a public health emergency which requires the use of the emergency rulemaking process. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule would increase access to this lifesaving drug faster, which would help relieve some stress on affected communities in Washington state and attempt to reduce opioid overdoses.

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	1	Amended	1	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

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

	New	0	Amended	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	1	Amended	1	Repealed	0

Date Adopted: December 8, 2023	**Signature:** 
Name: Kenneth Kenyon, PharmD, BCPS	
Title: Pharmacy Quality Assurance Commission Chair	

EXPEDITED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 23, 2023
TIME: 1:49 PM

WSR 23-22-035

Agency: Department of Health – Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) Updating reference to United States Pharmacopeia (USP) General Chapters 795 and 797. The Pharmacy Quality Assurance Commission (commission) is proposing a revision to WAC 246-945-100, Compounding minimum standards, to update the rule to the most recent version of the USP – National Formulary <795> and <797>.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule amends WAC 246-945-100 to update the rule to the most recent versions of the USP <795> and <797>. USP <795> and <797> were adopted into rule by reference effective on July 1, 2020. Since then, USP <795> and <797> have been updated.

Reasons supporting proposal: The existing reference in WAC 246-945-100 does not account for changes made to USP <795> and <797> that are official as of November 1, 2023 by USP. The proposed rule updates the references to the most recent versions. The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language incorporates by reference national standards without material change.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005 and 18.64.270

Is rule necessary because of a:

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

If yes, CITATION:

Name of proponent: (person or organization)

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Haleigh Mauldin	111 Israel Rd SE, Tumwater WA 98501	360-890-0720
Implementation:	Haleigh Mauldin	111 Israel Rd SE, Tumwater WA 98501	360-890-0720
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater WA 98501	360-480-9180

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

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

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

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

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

☐ Content is explicitly and specifically dictated by statute;

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

☐ Is being amended after a review under RCW 34.05.328.

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

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

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

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

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

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The proposed amendments adopt by reference, without material change, the most recent version of the national standard, USP <795> and USP <797>. The national standard is adopted by reference in exiting rule. The proposed amendments update the rule to the most recent version of the national standard.

NOTICE

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

Name: Haleigh Mauldin

Agency: Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia WA 98504-7852

Phone: 360-890-0720

Fax: N/A

Email: PharmacyRules@doh.wa.gov

Other: https://fortress.wa.gov/doh/policyreview

AND RECEIVED BY (date) 1/2/2024

Date: October 23, 2023 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission	**Signature:** 

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

WAC 246-945-100 Compounding minimum standards. (1) All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

(a) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations, official as of November 1, 2023;

(b) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, official as of November 1, 2023;

(c) USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings; and

(d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

EXPEDITED RULE MAKING

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 20, 2023
TIME: 5:41 PM

WSR 23-23-153

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: Citation and technical changes to pharmacy rules in chapter 246-945 WAC. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-001, 246-945-011, 246-945-014, 246-945-018, 246-945-063, 246-945-156, 246-945-170, 246-945-173, 246-945-175, 246-945-200, 246-945-217, 246-945-230, 246-945-417, and 246-945-590 to remove and replace citations to rules that have been repealed and make general grammatical and technical corrections.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The commission completed rulemaking in 2020, consolidating multiple chapters of rules that regulate the practice of pharmacy into one chapter, chapter 246-945 WAC. This proposal will remove citations to repealed WAC chapters, update citations to the current governing WAC chapter or specific rule(s) and make general grammatical corrections without making any material changes.

Reasons supporting proposal: Following the rules consolidation project that resulted in the creation of chapter 246-945 WAC in 2020, the commission discovered a number of cross-references that are now outdated. The Secretary also finalized updated fees for commission licensees since that time and updates are now needed to correct all fee rule references.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

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

If yes, CITATION:

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

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058

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

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

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

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

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

☐ Content is explicitly and specifically dictated by statute;

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

☐ Is being amended after a review under RCW 34.05.328.

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

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

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

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

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

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The commission believes the expedited rulemaking process is appropriate as the proposed rules fall under RCW 34.05.353(1)(c) since they "correct typographical errors... and clarify language of a rule without changing its effect." The updating of references from older repealed sections of rule to the current active sections of rule does not represent a substantive change to any regulation under the commission's jurisdiction.

NOTICE

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

Name: Joshua Munroe

Agency: Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia, WA 98504-7852

Phone: 360-502-5058

Fax:

Email: PharmacyRules@doh.wa.gov

Other: https://fortress.wa.gov/doh/policyreview

AND RECEIVED BY (date) 1/22/2024

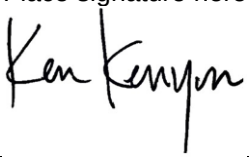
Date: November 20, 2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature:

Place signature here



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

WAC 246-945-001 Definitions. The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

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

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, ((~~and/~~)) or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" – United States Food and Drug Administration.

(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW 18.64.046 to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(37) "FPGEC" means foreign pharmacy graduate examination committee.

(38) "FPGEE" means foreign pharmacy graduate equivalency examination.

(39) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(40) "HIPAA" means Health Insurance Portability and Accountability Act.

(41) "Hospital" means any institution licensed under chapter 70.41 or 71.12 RCW or designated under RCW 72.23.020.

(42) "Hospital pharmacy" means that portion of a hospital licensed under RCW 18.64.043 which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(43) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system,

where the physical address of the office or clinic is identified on a hospital pharmacy license.

(44) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and ((~~technician(s)~~)) pharmacy ancillary personnel and interns.

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(45) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(46) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(47) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(48) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(49) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(50) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTP™).

(51) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(52) "Manual signature" means a printed or wet signature.

(53) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(54) "NABP" means the National Association of Boards of Pharmacy.

(55) "NDC" means National Drug Code.

(56) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(57) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(58) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(59) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(60) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(61) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(62) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(63) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(64) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(65) "Precursor drugs" as defined in chapter 69.43 RCW.

(66) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(67) "Protocol" means a written set of procedures, steps or guidance.

(68) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(69) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(70) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(71) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(72) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(73) "Secretary" means the secretary of the Washington state department of health.

(74) "Strength" means:

(a) The concentration of the drug product; ((~~and/~~)) or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(75) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(76) "USP" means the United States Pharmacopeia.

(77) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(78) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(79) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(80) "Virtual wholesaler" means an individual or facility that sells a prescription drug ((~~and/~~)) or device, but never physically possesses the product.

(81) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent ((~~and/~~)) or affiliated, or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any ((~~twelve~~)) 12 consecutive month period.

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

WAC 246-945-011 Prescription validity. (1) Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity.

(2) A prescription shall be considered invalid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in WAC 246-945-010;

(c) The prescription is expired; or

(d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308.

(3) A prescription is considered expired when:

(a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue.

(b) The prescription is for a noncontrolled legend drug or ((~~OTC's~~)) OTC and the date of dispensing is more than ((~~twelve~~)) 12 months after the prescription's date of issue.

AMENDATORY SECTION (Amending WSR 21-17-062, filed 8/11/21, effective 9/11/21)

WAC 246-945-014 Electronic prescribing mandate waiver. (1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other ex-

ceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.

(a) For economic hardship and ((~~technical~~)) technological limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:

(a) Economic hardship in the following circumstances:

(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;

(ii) Opening a new practice after January 1, 2020;

(iii) Intent to discontinue operating in Washington prior to December 31, 2022; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of ((~~thirty~~)) 30 percent medicaid patients.

(b) Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.

(c) Other exceptional circumstances include:

(i) The practitioner is providing services at a free clinic;

(ii) The practitioner generates fewer than ((~~one hundred~~)) 100 prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

(iii) The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or

(iv) Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Knowingly submitting a false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

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

WAC 246-945-018 Prescriptions—Labeling—Prepackage medications. Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, and medications dispensed by a pharmacy to a long-term care facility must include a label with the following information:

(1) Drug name;

(2) Drug strength;

(3) Expiration date in accordance with WAC 246-945-016(3);

(4) The manufacturer's name and lot number, if not maintained in a separate record; and

(5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.

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

WAC 246-945-063 Precursor definitions. The definitions in this section apply to WAC 246-945-065 through 246-945-088.

(1) "((~~Registered~~)) Restricted product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(2) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(3) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

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

WAC 246-945-156 Pharmacy intern—Temporary practice permit. (1) An individual that holds a pharmacy intern registration in another U.S jurisdiction, that has registration standards substantially equivalent to Washington, may request a temporary practice permit if:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any state;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) The applicant meets WAC 246-945-155 (1)(a) or (b).

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

(b) When a notice of decision on the pharmacy intern registration application is mailed to the applicant; or

(c) Ninety days after the temporary practice permit is issued. The applicant may obtain a one-time extension of up to ((~~ninety~~)) 90 days with approval of the commission.

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

WAC 246-945-170 Pharmacist licensure by license transfer—Temporary practice permits. (1) An individual who holds an active pharmacist license, in good standing, issued by another U.S. jurisdiction may apply for a pharmacist license in Washington by license transfer. In addition to the completion of the commission's application, the applicant must:

(a) File for license transfer using the NABP eLTP process; and

(b) Take and pass the approved jurisprudence examination.

(2) A temporary practice permit to practice pharmacy may be issued to an applicant for a pharmacist license by license transfer if the applicant meets all of the requirements and qualifications in subsection (1) of this section, and the following criteria are met:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any U.S. jurisdiction;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacist license is issued;

(b) When a notice of decision on the pharmacist license application is mailed to the applicant; or

(c) One hundred eighty days after the temporary practice permit is issued. The applicant may obtain a one-time extension of ((~~one hundred eighty~~)) 180 days with approval of the commission.

(4) A temporary practice permit holder cannot qualify as a responsible pharmacy manager.

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

WAC 246-945-173 Expired pharmacist license. To return to active status a pharmacist with an expired license shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 and:

(1) If the pharmacist license has been expired for less than three years the pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040 and ((~~fifteen~~)) 15 CPE hours per year the license has been expired.

(2) If the pharmacist license has been expired for three years or more, and the pharmacist holds an active credential in another U.S. jurisdiction, and is in good standing, the pharmacist shall:

(a) Meet the requirements ((~~in chapter 246-12 WAC, Part 2~~)) of WAC 246-12-040;

(b) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(c) Submit verification of current active pharmacy practice from another U.S. jurisdiction; and

(d) Take and pass the commission approved jurisprudence examination.

(3) If a pharmacist license has been expired for three years or more, and the pharmacist has not been in active practice in another U.S. jurisdiction, the pharmacist shall:

(a) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040;

(b) Serve an internship of ((~~three hundred~~)) 300 hours in compliance with WAC 246-945-163; and

(c) Take and pass the commission approved jurisprudence and licensure examinations.

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

WAC 246-945-175 Inactive pharmacist license. (1) A pharmacist may obtain an inactive license by meeting the requirements of WAC 246-12-090 and RCW 18.64.140.

(2) An inactive license can be renewed in accordance with ((~~chapter 246-12~~)) WAC 246-12-100 and by paying the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

(3) If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110.

(4) If a license is inactive for more than three years, and the pharmacist has been in active practice in another U.S. jurisdiction, to return to active status the pharmacist must:

(a) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(b) Submit verification of current active pharmacy from another U.S. jurisdiction;

(c) Meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110; and

(d) Take and pass the commission approved jurisprudence examination.

(5) If a pharmacist license has been inactive for more than three years, and the pharmacist has not been in active practice in another U.S. jurisdiction, to return to active status, the pharmacist shall comply with the requirements of WAC 246-945-173(3).

AMENDATORY SECTION (Amending WSR 23-09-062, filed 4/18/23, effective 5/19/23)

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

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

(3) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

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

WAC 246-945-217 Expired pharmacy technician certification. To return to active status a pharmacy technician with an expired certification shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992, and:

(1) If a pharmacy technician's certification has expired for five years or less, the pharmacy technician shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

(2) If the pharmacy technician's certification has expired for over five years and they have not been in active practice in another U.S. jurisdiction, the pharmacy technician shall:

(a) Complete the requirements for certification under WAC 246-945-205; and

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

(3) If the pharmacy technician's certification has expired for over five years and they have been in an active practice in another U.S. jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the pharmacy technician shall:

(a) Submit verification of current active pharmacy practice in another U.S. jurisdiction; and

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

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

WAC 246-945-230 General information, change of location, ownership or new construction. (1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

(a) "License" includes "licensing," "licensure," "certificate," "certification," and "registration."

(b) "Facility" includes pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

(2) The commission shall license a facility that:

(a) Submits a completed application for the license applied for on forms provided by the commission;

(b) Pays the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992. This fee will not be prorated under any circumstances;

(c) Undergoes an inspection by the commission if the facility is located in Washington pursuant to WAC 246-945-005 that results in either no deficiencies or an approved plan of correction; and

(d) Obtains a controlled substances registration from the commission and is registered with the DEA if the facility intends to possess or distribute controlled substances.

(3) Once an initial license is issued, a licensed facility must:

(a) Notify the commission and pay a facility inspection fee in lieu of paying an ((~~original~~)) initial license fee for modifications or remodels. A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.

(b) Submit a new application on forms provided by the commission and pay the ((~~original~~)) initial license fee as established in ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the ((~~original~~)) initial license fee in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than ((~~fifty~~)) 50 percent ownership in a corporation.

(i) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(ii) This agreement shall be provided to the commission upon request.

(d) Notify the commission within ((~~thirty~~)) 30 days of any changes to the information provided on their application.

(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(4) A license is issued to a location and is not transferable.

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

WAC 246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records. (1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care.

(a) Systems must prevent auto-population of user identification information.

(b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.

(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.

(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and

(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.

(4) The pharmacy shall have policies and procedures in place for system downtime.

(a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.

(b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed.

(c) This section does not require that a permanent dual recordkeeping system be maintained.

(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.

(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311.

(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections ((~~(2)~~)) (1) through ((~~(7)~~)) (6) of this section.

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

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ((~~as required to the FDA, commission and/or appropriate federal or state agency~~)) to the FDA, commission, and, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC ((~~246-960-330~~)) 246-945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Extension Process for Pharmacy Intern Renewal Limitation	*Number:* P013
References:	RCW 18.64.005; RCW 18.64.080; WAC 246-945-155	
Contact:	Marlee B. O'Neill, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	February 1, 2024	
Supersedes:	N/A	
Approved By:	Ken Kenyon, PharmD, BCPS Pharmacy Quality Assurance Commission Chair	

This policy statement establishes the approach of the Pharmacy Quality Assurance Commission (commission) to grant renewal extensions to pharmacy interns who have reached the renewal limitation set in WAC 246-945-155(3).

RCW 18.64.080(3) states all registrations issued to pharmacy interns shall be valid for a period to be determined by the commission, but in no instance shall the registration be valid if the individual is no longer making timely progress toward graduation.

Chapter 246-945 WAC, the Commission's new rules chapter, went into effect on July 1, 2020. It replaced all former requirements, including those of pharmacy intern registrations. The new rule states that pharmacy intern registrations may be renewed twice following issuance. Issued registrations are valid for two years (WAC 246-945-990). Each registrant may therefore hold an active pharmacy intern registration for a total of approximately six years.

The commission is aware that due to unforeseen circumstances, pharmacy interns are not always able to complete their internship hours prior to their registration expiring after having held it for six years. The commission authorized rulemaking to explore extending the two-time renewal limit. However, while rulemaking is in progress, the commission will consider requests from pharmacy interns to allow them to renew their registration beyond six years if the commission determines there is good cause to do so. "Good cause" includes, but is not limited

to, a serious health issue or needing to care for a family member with a serious health issue. Pharmacy interns must still meet all other requirements in RCW 18.64.080 and WAC 246-945-155.

To request an extension, a pharmacy intern must email WSPQAC@doh.wa.gov with the following information:

- Name;
- Intern registration number;
- Intern registration expiration date;
- Explanation of the reason for the request; and,
- Documentation for how the intern meets all other requirements of RCW 18.64.080 and WAC 246-945-155.

The commission will make every effort to timely process these requests; however, requestors should assume that these requests take up to 60 days to process.

Finally, the Commission has begun to engage in rulemaking to consider amending WAC 246-945-155 in order to, among other things, convert this policy statement into rule.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Temporary Practice Permits for Military Spouse Pharmacy Interns	*Number:* P011
References:	RCW 18.64.080(3); RCW 16.340.020; WAC 246-945-155; WAC 246-945-156	
Contact:	Marlee B. O'Neill, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	February 1, 2024	
Supersedes:	N/A	
Approved By:	Ken Kenyon, PharmD, BCPS Pharmacy Quality Assurance Commission Chair	

As of February 1, 2024, the Pharmacy Quality Assurance Commission (commission) will issue *temporary* pharmacy intern practice permits for 180 days to applicants who are spouses of military personnel and who meet the criteria in RCW 18.340.020(1)(a).

RCW 18.64.080(3) allows all pharmacy intern licenses to be valid for a period to be determined by the commission, but in no instance shall the certificate be valid if the individual is no longer making timely progress toward graduation. In accordance with WAC 246-945-155, individuals are required to register with the commission as a pharmacy intern before beginning pharmacy practice experiences in Washington. Additionally, WAC 246-945-156(3) states that pharmacy intern temporary practice permits will expire ninety days after the permit is issued and the applicant may obtain a one-time extension of up to ninety days with approval of the commission.

House Bill 1009 - Concerning Military Spouse Employment (Chapter 165, Laws of 2023) went into effect on July 23, 2023. Section 4 of the bill took effective on October 1, 2023, and requires the Commission to issue temporary practice permits for a minimum of 180 days to applicants who are spouses of military personnel subject to a military transfer, and who are licensed, certified, or registered in another state to perform professional services in that state.

The pharmacy intern license is the only temporary practice permit for spouses of military personnel issued by the Commission that is not currently issued for a minimum of 180 days. Based on the implementation of House Bill 1009, the Commission will issue pharmacy intern temporary practice permits for 180 days to applicants who are spouses of military personnel and who meet the criteria in RCW 18.340.020(1)(a), by February 1, 2024.

Finally, the Commission has begun to engage in rulemaking to consider amending WAC 246-945-155 and WAC 246-945-156 to, among other things, convert this policy statement into rule.

8. Legislative Session Bill Report

Link to Washington State Legislature Bill Information 2024

January 8, 2024 – First day of session.
January 31, 2024 – Policy Committee Cutoff. **Next cutoff**
February 5, 2024 – Fiscal Committee Cutoff.
February 13, 2024 – House of Origin Cutoff.
February 21, 2024 – Policy Committee Cutoff – Opposite House.
February 26, 2024 – Fiscal Committee Cutoff – Opposite House.
March 1, 2024 – Opposite House Cutoff.
March 7, 2024 – Sine die. Last day allowed for regular session under state constitution.

TVW - http://www.tvw.org/

Bill Tracker			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
SHB 1909 Joshua	Relating to membership of the Pharmacy Quality Assurance Commission	HB 1909 amends RCW 18.64.001 pertaining to individual eligibility to apply for a seat on the Pharmacy Quality Assurance Commission (commission). The amended bill changes one of seats reserved only for a licensed pharmacist to allow for a public member who "may be an owner, officer, or operator of a pharmacy, but may not be licensed as a pharmacist or pharmacy technician" to also apply for the seat.	**HB 1909** *Sponsors:* Representatives Low, Ramel, Schmidt, Timmons, and Schmick *Public Hearing (Health Care & Wellness)*: 1/9/2024 *Executive Session (Health Care & Wellness)*: 1/24/2024; amendment language adopted; **passed through committee by majority vote**; referred to Rules 2 Review (1/29)
SSB 5776 Joshua	Emergency supply of insulin	The bill adds new sections to chapter 70.330 RCW pertaining to providing one emergency 30-day supply of insulin to patients within a 12-month period. The Health Care Authority (HCA) is tasked with implementing the emergency insulin program. The substitute bill requires the HCA to use the prescription drug purchasing consortium to manage the program. Network pharmacies may submit a request for reimbursement to the consortium for any emergency insulin dispensed under the program. The consortium will invoice manufacturers quarterly for the cost of insulin dispensed by those network pharmacies. Under the substitute bill, the HCA must also post a list of manufacturer patient cost savings programs on its website alongside the other explanatory information about the emergency insulin provision program.	**SB 5776** *Sponsors*: Senators Keiser, Cleveland, Randall, Van De Wege, Conway, Dhingra, Kauffman, Hasegawa, Hunt, Kuderer, Lovick, Mullet, Nguyen, Nobles, Salomon, Stanford, Valdez, and C. Wilson *Second Executive Session (Health & Long Term Care)*: 1/25/2024; amendment language adopted; **passed through committee by majority vote**; referred to Ways & Means (1/26) *Public Hearing (Ways & Means)*: 2/2/2024

Bill Tracker			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
SHB 2115 Joshua	Prescription labels for medications used for abortion	The bill amends RCWs 18.64.246 and 69.41.050 to allow prescribers to request that the prescription label for abortion medications list the prescriber's national practitioner identification number or health care facility name instead of the name of the prescriber. For both statutory sections, "abortion medications" is defined as substances used in the course of medical treatment intended to induce the termination of a pregnancy including, but not limited to, mifepristone. The substitute version of the bill replaces the term "national practitioner identification number" with "national provider identifier."	**HB 2115** *Sponsors*: Representatives Thai, Slatter, Senn, Chapman, Reed, Ramel, Macri, Gregerson, Doglio, Fosse, Riccelli, Wylie, and Reeves *Executive Session (Health Care & Wellness)*: 1/17/2024; no action taken *Second Executive Session (Health Care & Wellness)*: 1/19/2024; **substitute bill introduced and adopted; substitute bill passed through committee by majority vote;** referred to Rules 2 Review (1/22)
SB 5960 Joshua	Prescription labels for medications used for abortion	Companion bill to HB 2115	**SB 5960** *Sponsors*: Senators Frame, Dhingra, Hasegawa, Hunt, Keiser, Kuderer, Liias, Nobles, Salomon, Stanford, Valdez, and C. Wilson *Executive Session (Health & Long Term Care)*: 1/23/2024; **passed through committee by majority vote**; referred to Rules Committee for second reading (1/24)
HB 2116 Joshua	Pharmacist prescriptive authority	HB 2116 amends the definition for "Practice of pharmacy" in RCW 18.64.011(28) to grant pharmacists the authority to prescribe and order drugs and devices as authorized by the Pharmacy Quality Assurance Commission (commission) in rule. The commission is tasked with conducting rulemaking, to be completed by July 1, 2026, to further define prescriptive authority for pharmacists.	**HB 2116** *Sponsors*: Representatives Thai, Slatter, Senn, Reed, Ormsby, Macri, Gregerson, Fosse, and Wylie *Introduced (House)*: 1/8/2024, referred to Health Care & Wellness Committee *Public Hearing (Health Care & Wellness*): 1/24/2024

Bill Tracker			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
SB 6019 Joshua	Pharmacist prescriptive authority	Companion bill to HB 2116	**SB 6019** *Sponsors*: Senators Muzzall, Braun, Frame, and Short *Introduced (Senate)*: 1/8/2024, referred to Health & Long Term Care Committee
SSB 5853 Joshua	Extending the crisis relief center model to provide behavioral health crisis services to minors.	Last session, the legislature passed Second Substitute Senate Bill 5120 (chapter 433, Laws of 2023) regulating crisis relief centers. The bill only included adults as the population who can be served in these facilities. This year's bill adds the ability for a crisis relief center to serve minors and requires that adults and minors be served in separate facilities. The substitute version amends some definitions and adds 23-hour crisis relief centers to various facility requirements in chapter 71.34 RCW.	**SB 5853** *Sponsors*: Senators Dhingra and Wagoner *Public Hearing (Health & Long Term Care)*: 1/11/2024 *Executive Session (Health & Long Term Care)*: 1/16/2024; **substitute version introduced and passed through committee;** referred to Ways & Means (1/17)
SHB 1889 Haleigh	Allowing persons to receive professional licenses and certifications regardless of immigration or citizenship status	HB 1889 amends RCW 18.130.040 regarding eligibility status for individuals seeking a license as allowed under Title 8 U.S.C. Sec. 1621. The bill states disciplining authorities cannot deny a license solely on the basis of a person's immigration or citizenship status. This includes licenses under the regulatory jurisdiction of the commission as defined in chapter 18.64 RCW and chapter 18.64A RCW for pharmacist, pharmacy intern, pharmacy technician, and pharmacy assistant licenses. The substitute bill amends other statutes to align other professions with the proposed changes regarding license eligibility conditions.	**HB 1889** *Sponsors*: Representatives Walen, Taylor, Leavitt, Slatter, Ramel, Duerr, Ryu, Ramos, Bateman, Reeves, Reed, Ormsby, Callan, Peterson, Kloba, Macri, Street, Doglio, Bergquist, Mena, Goodman, Thai, Santos, Hackney, Pollet, Fosse, Davis, Senn *Second Executive Session (Consumer Protection & Business):* 1/19/2024; no action taken *Third Executive Session (Consumer Protection & Business):* 1/26/2024; **substitute version introduced and passed through committee;** referred to Rules 2 (1/29)

Bill Tracker			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
SB 5977 Haleigh	Limited legalization of psilocybin services	SB 5977 adds a new section to RCW 69.50 relating to limited legalization of psilocybin services in Washington state. The bill allows for nonprofit organizations to facilitate psilocybin services in order to promote wellness. The bill allows the nonprofit organizations to purchase, receive, possess, cultivate, deliver, or dispose of psilocybin or psilocybin mushrooms.	**HB 5977** *Sponsors:* Senators Salomon, Rivers, Frame, Schoesler, Wellman *Introduced (House)*: 1/8/2024, referred to Health & Long Term Care Committee
SB 6144 Julia	Establishing a Prescribing Psychologist Certification	SB 6144 amends chapter 18.83 RCW to establish for a certification for prescribing psychologists. The bill authorizes prescribing psychologists to prescribe, administer, discontinue, and distribute controlled substances to treat mental illnesses. The bill also amends the definition of practitioner in RCW 18.64.011 to include prescribing psychologists.	**SB 6144** *Sponsors:* Senators Randall, Rivers, Muzzall, Dhingra, Robinson, Van De Wege, Conway, Frame, Lovick, Nguyen, Nobles, Saldaña, and C. Wilson *Introduced (Senate):* 1/10/2024, referred to Health & Long Term Care Committee *Public Hearing (Health & Long Term Care):* 1/19/2024
ESSB 5481 Joshua	Uniform Telehealth Act	This bill adds a new chapter to Title 18 RCW to establish guidelines for practitioners to provide telehealth services to patients in Washington. Practitioners must provide telehealth services in compliance with the professional practice standards of practitioners who provide in-person health care in the state. Out-of-state practitioners wishing to use telehealth must hold a current license or certification required to provide health care in this state. Care must occur at the patient's location at the time the service is provided. Washington disciplinary authorities may not establish different professional practice standards for telehealth care nor limit the telecommunication technology required to provide telehealth services. The collaborative for the advancement of telehealth must review the proposal authored by the uniform law commission that establishes guidelines for out-of-state health care providers to register with the disciplinary authority regulating their profession. The collaborative must submit their recommendations to the legislature by December 1, 2024.	**SB 5481** *Sponsors*: Originally sponsored by Senators Cleveland and Pedersen; by request of Uniform Law Commission *Re-introduced (Senate)*: 1/8/2024, referred to Rules Committee; placed on second reading by Rules (1/17) *Second Reading (Rules)*: 1/24/2024, **substitute bill presented and adopted** *Floor Vote (Senate)*: 1/24/2024, floor amendments adopted; **passed through chamber by majority vote (49/0/0/0)**

Agency Request Bills			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
ESSB 5271 Joshua	Uniform Facilities Enforcement Framework	This bill was originally introduced during the 2023 session. It extends the enforcement tools enacted in 2020 and 2021 for psychiatric and acute care hospitals to all facilities the department regulates. Our current enforcement options for most facilities are limited to denying, suspending, or revoking a license. This bill adds: • Immediate enforcement tools, such as stop placement, limited stop placement, limited stop service, and reasonable conditions, to address violations that constitute immediate jeopardy, including when a facility refuses to comply with an investigation. Immediate jeopardy is defined as a situation in which the facility has placed patients in its care at risk for serious injury, serious impairment, or death. • Intermediate tools to address repeat violations to bring facilities into compliance with regulations. These tools, including reasonable conditions and civil fines, are intended to be used after the department's initial informal process of issuing a statement of deficiencies and a facilities' plan of correction fail to ensure the violation does not occur again. The legislation also ensures the authority to issue cease and desist orders and injunctions for unlicensed operation of a facility is consistent for all facilities the department regulates.	**ESSB 5271** *Sponsors:* **originally sponsored by** Senators Cleveland, Robinson, Kuderer, Nobles, Wellman, and C. Wilson; by request of Department of Health *Re-introduced (Senate)*: 1/8/2024, retained in present status, referred to Rules Committee; placed on second reading (1/17) *Floor Vote (Senate)*: 1/24/2024, amendment language adopted; **passed through chamber by majority vote (29/20/0/0)**
HB 2157 Joshua	Vaccine definition	This bill updates the definition for "vaccine" in RCW 70.290.010 to include all FDA-approved immunizations recommended by the centers for disease control and prevention.	**HB 2157** *Sponsors:* Representatives Harris, Stonier, Reed, Ormsby, Macri, Ortiz-Self, and Reeves; by request of Department of Health

Agency Request Bills			
Bill # / Staff Lead	**Short Title**	**Brief Description**	**Committee Action (subject to change)**
			Executive Session (Health Care & Wellness): 1/17/2024; no action taken *Second Executive Session (Health Care & Wellness)*: 1/19/2024; **passed through committee by majority vote**; referred to Rules 2 Review (1/22)
SB 5982 Joshua	Vaccine definition	Companion bill to HB 2157	**SB 5982** *Sponsors*: Senators Cleveland, Robinson, Keiser, Dhingra, Van De Wege, Conway, Frame, Kuderer, Liias, Mullet, Nobles, Salomon, Trudeau, Valdez, and Wellman; by request of Department of Health *Executive Session (Health & Long Term Care)*: 1/16/2024; **passed through committee by majority vote**; passed to Rules Committee for second reading (1/17) *Second Reading (Rules)*: 1/24/2024
SB 6095 Joshua	Establishing clear authority for the Secretary of Health to issue standing orders	The bill allows the secretary of health or the secretary's designee to issue a standing order pertaining to "any biological product, device, or drug for purposes of controlling and preventing the spread of, mitigating, or treating any infectious or noninfectious disease or threat to the public health." The bill outlines the conditions and limitations relating to the ability to issue such standing orders.	**SB 6095** *Sponsors*: Senators Robinson and Valdez; by request of Department of Health *Public Hearing (Health & Long Term Care)*: 1/18/2024 *Executive Session (Health & Long Term Care)*: 1/26/2024; referred to Rules Committee for second reading (1/29)

Additional Bills to Watch		
Bill # /Companion	**Short Title**	**Committee Action (subject to change)**
SSB 5804	Opioid overdose reversal medication in high schools	**SSB 5804** *Sponsors*: Senators Kuderer and Wellman *Executive Session (Early Learning & K-12 Education)*: 1/17/2024; **substitute bill proposed and accepted**; passed to Rules Committee for second reading (1/18) *Second Reading (Rules)*: 1/24/2024
HB 1954	Reproductive health care services and gender-affirming treatment	**HB 1954** *Sponsors*: Representatives Riccelli, Bateman, Ramel, Reed, Simmons, Ormsby, Macri, Doglio, Thai, Lekanoff, and Reeves *Second Executive Session (Health Care & Wellness)*: 1/19/2024; **passed through committee by majority vote**; referred to Rules 2 Review (1/22) *Floor Vote (House)*: 1/25/2024; **passed through chamber by majority vote (56/37/0/5)** *First Reading (Senate):* 1/26/2024; referred to Health & Long Term Care
HB 2241	Prohibiting puberty blocking medications, cross-sex hormones, and gender transition surgeries for minors	**HB 2241** *Sponsors*: Representative Jacobsen, Christian *Introduced (House)*: 1/9/2024, referred to Health Care & Wellness Committee
SB 6178	Prescriptive authority for licensed midwives	**SB 6178** *Sponsors*: Senators Randall, Torres, Nobles, Trudeau, Kuderer, Dhingra, Saldaña, Shewmake, and C. Wilson *Public Hearing (Health & Long Term Care)*: 1/19/2024 *Executive Session (Health & Long Term Care)*: 1/23/2024; **passed through committee by majority vote**; passed to Rules Committee for second reading (1/24)

Dead/dormant Bills (relevant if needed to pass the budget)		
Bill # /Companion	**Short Title**	**Bill Summary**