2025
NUCLEAR PHARMACY DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Failure to complete this form by July 1, 2025, and within 15 days of becoming PIC, may result in disciplinary action (OAR 855-115-0210(1)(h)) .

In order to be a PIC, a pharmacist must have (OAR 855-115-0205(1)(a)(b)(c)):

- **Completed at least one year of pharmacy practice; or**
- **Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and**
- **Be employed by the outlet. (OAR 855-115-0205(1)(a)(b))**

Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years OAR 855-115-0205(3))

Requirements: Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the board immediately upon request at the time of inspection and retained in compliance with OAR 855-104-0055.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

Internal Use: Following completion of the self-inspection form, ensure it is signed and dated by the PIC, reviewed with all pharmacy staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

Agency Use: During an inspection, Compliance Officers use the self-inspection form as a general guide to assess compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and any auxiliary documents referenced within at the time of inspection.

Email all compliance-related questions to: pharmacy.compliance@bop.oregon.gov

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The PIC must complete and sign this inspection form and have available for inspection **within 15 days of becoming PIC and by 7/1/2025** (as required by OAR 855-115-0210).

Date PIC completed Self-Inspection: _____ / _____ / _____

PIC Name: _____ License #: _____

PIC **Work** E-mail: _____

Pharmacy Name: _____

Address: _____

City: _____ State: h_____ Zip Code: _____

Telephone: (_____) _____-_____ Fax: (_____) _____-_____

DEA #: _____ EXP: _____ / _____ / _____

Institutional Drug Outlet Registration #: _____ EXP: _____ / _____ / _____

Retail Drug Outlet Registration #: _____ EXP: _____ / _____ / _____

Manufacturer Registration #: _____ EXP: _____ / _____ / _____

Wholesaler Registration #: _____ EXP: _____ / _____ / _____

Hours of operation: _____

Please list where the following items are specifically located inside the pharmacy. Once located, ensure each is compliant, and reflects currents practices within the outlet (if an item is not applicable, indicate with N/A). Unless otherwise specified, documents are to be retained for 3 years (the first of which must be on site) and must be provided to the Board upon request, as outlined in OAR 855-104-0055.

Initial and Ongoing Training and Certificates

- Nuclear Pharmacy Certification by the Board of Pharmaceutical Specialties
- Nuclear Pharmacy Training Certificates
- Letter of Notification/Permission from the Board of Pharmacy
- Technician Training Documents
- Drug Storage Training Documents

- Sterile Compounding
    - Media Fill / Gloved Fingertip Competency
- Initial and Ongoing Training, Certificates and Documentation

Policies and Procedures

- Current Written Drug Outlet Policies and Procedures
- Creating Compounding and Master Formulation Records (with documented pharmacist approval)
- Hygiene
- Cleaning Activities (to include sanitizing and disinfecting)
- Gowning and Garbing
- Material Selection, Handling, and Storage
- Handling, Packaging, Storage, and Transport of completed compounded preparations.
- Continuous Quality Assurance and Quality Control (to include release-testing, end-product evaluation, and quantitative/qualitative testing)
- Adverse Event Reporting and Recalls
- Training, Evaluation and Requalification
    - Aseptic Manipulation Skills Testing, Gloved Fingertip testing and related assessments
- Creating Compounding and Master Formulation Records (with documented pharmacist approval)

Testing (equipment, environmental, and product)

- Equipment Certifications and Calibrations
- Environmental Monitoring (air and surface sampling for viable and non-viable particles, as appropriate)

- Bulk Chemical Certificates of Analysis

Controlled Substance Records (for the last 3 years)

- Annual Controlled Substance Inventories and Reconciliations
- C-II Reconciliations (as applicable)
- Completed C-II Order Forms (DEA 222 or CSOS)
- C-II Invoices
- C-III through C-V Invoices
- DEA Form 106
- Invoices for Controlled Substance Returns (to include executed DEA 222 Forms for reverse distribution)

Records

- Cleaning Logs
- Master Formulation Records
- Compounding Worksheets

Compounding References (please list name(s) and location):

INSTRUCTIONS:
Verify compliance of each section by marking the corresponding box. Should any non-compliance be identified, rectify the deficiencies and record the correction date**.**

General Requirements

Yes	No			Rule Reference
☐	☐	1	Has each nuclear pharmacist met all Board of Pharmacy requirements for practicing nuclear pharmacy, pertaining to the following elements? (mark box once verified) • Training • Education • Experience • Letter of approval from the Board of Pharmacy (BOP) **Attach BOP notification letters for all pharmacists.**	OAR 855-042-0010
☐	☐	2	Are the following current, and conspicuously posted? (mark box once verified) ☐ Pharmacy registration(s) ☐ DEA registration ☐ Pharmacist license(s) ☐ Preceptor license(s) ☐ Intern license(s) ☐ Technician license(s) ☐ Laboratory license (if applicable)	ORS 689.615 OAR 855-115-0105(11) OAR 855-120-0105(3)(i) OAR 855-120-1070(3)(a) OAR 855-125-0105(3)(j) OAR 855-041-1190(2)(a)
☐	☐	3	Do the outlet's policies and procedures address **at least** all of the following minimum requirements? (mark box once verified) ☐ Security ☐ Sanitation ☐ Drug and/or device: ☐ Procurement ☐ Receiving ☐ Storage ☐ Dispensing ☐ Delivery ☐ Disposal (including hazardous and Rx waste) ☐ Operation, testing and maintenance of pharmacy systems and equipment ☐ Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process ☐ Initial **and** ongoing training ☐ Pharmacist supervision, direction, and control of non-pharmacists ☐ Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians (to include "final verification and/or vaccination, if performed) ☐ Utilization of Oregon-licensed pharmacists (i.e. DUR, Counseling, etc.) ☐ Interpretation, translation, and prescription reader services ☐ Patient confidentiality ☐ Recordkeeping	OAR 855-041-1040

Yes	No			Rule Reference
			☐ Continuous quality improvement ☐ Plan for discontinuing and recovering services in the event of a pharmacy closure	
☐	☐	4	Are the following minimum references and equipment available? • Current BOP laws and rules • Oregon Radiation Control regulations • CFR Title 10, Parts 0-199 • CFR Title 49, Parts 106-199 • USP 825 • Sink (with both hot & cold water) • Refrigeration	OAR 855-042-0015 OAR 855-042-0025
☐	☐	5.	Is the pharmacy in compliance with USP 825?	
		6.	How often are the hoods certified? _____ **Last hood certification date: _____/_____/_____**	
		7.	How are prescription and medication records securely maintained? _____ _____ _____ Who has keys to the pharmacy, and is pharmacy access only permitted when a pharmacist is present? _____ _____ _____	OAR 855-042
☐	☐	8.	Is Drug Handling conducted in compliance with all regulations? • Dating • Disposal containers	OAR 855-042
☐	☐	9.	Do **inner labels** contain all of the following required elements? • Name of the nuclear pharmacy • Name of the radiopharmaceutical • Prescription number • Date • Standard radiation symbol • The words “Caution - Radioactive Material” • Amount of radioactivity material contained in millicuries, microcuries, or their SI equivalent	OAR 855-042-0015(10)(a-g)
☐	☐	10	Do **outer labels** contain all of the following required elements? • Prescription number and the patient’s name, or the words “Physician Use Only” in the absence of the name of the patient	OAR 855-042-0015(9)(a-k)

Yes	No			Rule Reference
			• Standard radiation symbol • The words “Caution – Radioactive Material” • Name of the radiopharmaceutical • Lot number • Amount of radioactivity material contained in millicuries, microcuries, or their SI equivalent • If a liquid, the volume in milliliters • The requested calibration date and time • Expiration date and/or time (if applicable) • Specific concentration of radioactivity • Name & address of the practitioner and/or institution that ordered the radiopharmaceutical • Standard non-radiopharmaceutical labeling	
☐	☐	11	Do all prescription records include the following? • Name of prescriber and/or institution • Name of radiopharmaceutical • Amount of radioactivity or SI equivalent • Date, time, and volume of calibration	OAR 855-042-0015(8)(a-d)

General Compounding Requirements

Yes	No	N/A			Rule Reference
☐	☐	☐	12.	Does the pharmacy have access to the most current USP Chapters? **Note:** The Board has adopted USP <825> (01/01/2024)	OAR 855-041-1035 OAR 855-045-0200 OAR 855-045-0205
☐	☐	☐	13.	Does the pharmacy have compounding accreditation? If yes, please specify (e.g., NABP, PCAB, Joint Commission): _____ **Date of the last accreditation:** _____ / _____ / _____ ***(Attach a copy of last accreditation to this form)***	
		☐	14.	What type of sterile compounding is performed? (check all that apply) ☐ IV’s ☐ TPN ☐ Intrathecal / Epidural ☐ Eye Drops ☐ Lyophilization ☐ Pellets ☐ Chemotherapy ☐ Hazardous ☐ Other: _____	

Compounding Policies and Procedures

Yes	No	N/A			Rule Reference
☐	☐	☐	15.	Describe the pharmacy's process for the supervision of compounding by technicians. _____ _____ _____ **Note:** A technician may only compound under the supervision, direction, and control of a pharmacist.	ORS 689.486(6)
☐	☐	☐	16.	Does the pharmacy have standard operating policies and procedures for the following? (mark each box once confirmed) ☐ Continuous quality assurance/ quality control ☐ Cleaning, testing, and calibration of all equipment and devices ☐ Establishing beyond-use dates (BUDs) for compounded products ☐ Extending BUDs ☐ N/A ☐ Adverse event reporting and recalls (to include notifying the Board of a patient-level recall within 10 working days)	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	17.	If the pharmacy extends BUDs beyond USP standards, please describe the QA process utilized to ensure sterility and/or stability are maintained: _____ _____ _____ How often are samples sent for testing to an independent laboratory to account for the facility's unique processes? _____ _____	OAR 855-045-0220

Compounding Operations

Yes	No	N/A			Rule Reference
☐	☐	☐	18.	Are bulk drug substances acquired **only** from Board-registered manufacturers or wholesalers, and have the required certificate of analysis?	e-CFR 503A Guidance Document 503B Guidance Document
☐	☐	☐	19.	Is the pharmacy **only** using active pharmaceutical ingredients (APIs) and excipients that are approved for use in humans, not laboratory/research grade products?	e-CFRs
☐	☐	☐	20.	Does the pharmacy batch compound products? If so, what type(s)? ☐ Sterile ☐ Non-sterile	

Yes	No	N/A			Rule Reference
☐	☐	☐	21.	If yes, is the pharmacy currently in compliance with USP 825?	OAR 855-045-0200

Compounding Records

Yes	No	N/A			Rule Reference
☐	☐	☐	22.	Do the master formulation records include the following required elements, where appropriate? (mark each box once confirmed) ☐ Complete instructions for preparing the product, including equipment, supplies, and description of compounding steps ☐ Ingredients, quantities, and calculations used to determine/verify those amounts ☐ Sterilization method, if required (such as steam, dry heat, radiation, filtration, etc.) ☐ Quality control procedures and expected results ☐ Compatibility and stability information, including references ☐ BUD and storage requirements, including references ☐ Appropriate ancillary information such as cautionary statements, hazardous drug warning labels, etc. ☐ Name, strength, dosage form, and physical description of the final preparation **Note:** Be prepared to provide documentation at the time of inspection.	OAR 855-045-0270
☐	☐	☐	23.	Do completed compounding records include all of the following required elements? (mark each box once confirmed) ☐ Master formulation record reference for the preparation, when applicable ☐ Name, quantity (weight or measurement), manufacturer's lot number and expiration date for all ingredients used, including base, diluent, primary excipient, etc. ☐ Identity of all personnel involved in each step of the process ☐ Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used ☐ Name, strength, dosage form, and physical description of final preparation ☐ Date and **time prepared** ☐ Quantity prepared ☐ Pharmacy unique lot number ☐ BUD and storage requirements (with reference, if different from master formulation record) ☐ Documentation of any quality control issues, adverse reactions, or preparation problems (including those reported by the patient, caregiver, or other person), with corresponding corrective actions ☐ Records of compound dispensation or transfer ☐ Any other information, as required by pharmacy policies and procedures	OAR 855-045-0270

Compounded Sterile Products (CSP's) General Requirements ☐ N/A

Yes	No			Rule Reference
		24.	How often does the pharmacy test **all** compounding personnel (including verifying pharmacists) in aseptic manipulative skills, gowning and garbing, and gloved fingertip sampling? _____ _____	OAR 855-045-0220 OAR 855-045-0270
☐	☐	25.	Do compounding procedures include requirements for use of gowns, shoe covers, hair covers, sterile gloves, and masks? **Note**: Makeup, jewelry, and artificial nails/fingernail polish are not permitted in the buffer room.	OAR 855-045-0220 OAR 855-045-0200
☐	☐	26.	Are CSP's prepared in an ISO 5 certified Primary Engineering Control (PEC)?	OAR 855-045-0200
☐	☐	27.	Are all ISO classified areas checked and certified per USP standards every 6 months and whenever a PEC is relocated, or the physical structure of the buffer room or anteroom has been altered?	OAR 855-045-0220
☐	☐	28.	Have the ISO classified areas had any growth above action levels in the past year? If yes, please identify the date and steps taken to remediate. _____ _____ _____ _____	OAR 855-045-0220 OAR 855-045-0270
☐	☐	29.	Have there been any other issues identified in the ISO classified spaces in the past year? If yes, please explain. _____ _____ _____ _____	OAR 855-045-0200
☐	☐	30.	Is ISO determination taken under dynamic conditions while simulated compounding is occurring?	OAR 855-045-0200
☐	☐	31.	Are surfaces and equipment in buffer room and anteroom nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants?	OAR 855-045-0200
☐	☐	32.	Does the pharmacy document environmental monitoring to ensure that the compounding environment is properly maintained, including temperature, humidity, and pressure differentials?	OAR 855-045-0270
☐	☐	33.	Does the pharmacy have policies and procedures that include routinely monitoring the compounding environment for microbial or fungal growth?	OAR 855-045-0220 OAR 855-045-0270

Yes	No			Rule Reference
		34.	How often does the pharmacy perform surface sampling? _____ _____ What is the incubation **time** and **temperature**? _____ _____	OAR 855-045-0220 OAR 855-045-0270
☐	☐	35.	In addition to regular labeling requirements, do CSP labels include all of the following elements? (mark each box once confirmed) ☐ The generic or official name of each active ingredient ☐ The strength or concentration of each active ingredient (to include primary solution for a sterile parenteral preparation) ☐ The dosage form and route of administration ☐ Rate of infusion (for a sterile parenteral preparation) ☐ The total quantity of the drug product ☐ A BUD, compliant with current USP standards ☐ Storage and handling instructions, cautionary information or warnings as necessary to promote proper and safe use, and any relevant drug-specific information?	OAR 855-045-0240
☐	☐	36.	In ISO 7 and 8 areas, are floors and work surface areas cleaned **daily,** and are walls, ceilings, and shelving cleaned at least **monthly**?	OAR 855-045-0200
☐	☐	37.	Who performs cleaning and disinfecting of ISO classified areas in the pharmacy? _____ Are these individuals trained in accordance with USP 797 and USP 825?	OAR 855-045-0220 OAR 855-045-0270
		38.	What agents are used to clean and disinfect the PEC? _____ _____ _____ How often are they used? _____ _____ _____ What is the dwell time? _____ _____ _____	OAR 855-045-0220 OAR 855-045-0270

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, that written policies and procedures reflect current practices, and that the answers marked on this form are true and correct.

Date: _____ / _____ / _____

Signature of PIC: _____

Printed Name of PIC: _____

PHARMACY PERSONNEL—KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED

Have each licensee review this inspection form, corresponding documents, and procedures, and be prepared to assist in locating information during an inspection.

NAME	OREGON LICENSE #	EXP. DATE	BOARD of PHARMACEUTICAL SPECIALTY CERT # and EXP. DATE