2024
NUCLEAR PHARMACY DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

- Failure to complete this form by July 1, 2024, 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:
  - 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)(c))

- Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years. (OAR 855-0115-0205(2))

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 pharmacy compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and locate any auxiliary documents referenced within at the time of inspection.

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

The PIC must complete and sign this inspection form and have available for inspection **within 15 days of becoming PIC and by 7/1/2024** (as required by OAR 855-115-0210).

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

PIC Name: _____ PIC License #: _____

PIC **Work** E-mail: _____

Pharmacy Name: _____

Address: _____

City: _____ State: _____ 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

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 Control (to include release-testing, end-product evaluation, quantitative/ qualitative testing, etc.)
- Adverse Event Reporting and Recalls

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 / Reconciliations
- C-II Reconciliations (whether performed quarterly or monthly)
- Completed C-II Order Forms (DEA 222/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

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies and write the date of correction, if applicable.

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? • Training • Education • Experience • Letter of approval from the Board of Pharmacy (BOP) **** Please attach BOP notification letters for all pharmacists. ****	OAR 855-042-0010
☐	☐	2	Are the following current, and conspicuously posted? (check 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? • Security • Sanitation • Drug and/or device: o Procurement o Receiving o Storage o Dispensing o Delivery o 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	OAR 855-041-1040

Yes	No			Rule Reference
			• 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 • Continuous quality improvement • Plan for discontinuing and recovering services in the event of a pharmacy closure ****Please Attach DUR policy and procedure. ****	
☐	☐	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 permitted when a pharmacist is not 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"	OAR 855-042-0015(10)(a-g)

Yes	No			Rule Reference
			• Amount of radioactivity material contained in millicuries, microcuries, or their SI equivalent	
☐	☐	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 • 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	OAR 855-042-0015(9)(a-k)
☐	☐	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)

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

Date: _____ **/** _____ **/** _____

Printed Name of PIC: _____

Signature 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 and sign below certifying their review.

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