

Requirements for Ohio Nuclear Pharmacies

Updated 1/6/2022

This guidance applies to in-state nuclear pharmacies that prepare radiopharmaceuticals. A separate guidance for non-resident nuclear pharmacies is available here: www.pharmacy.ohio.gov/NRPnuclear

Effective February 1, 2022, the following nuclear pharmacy rules go into effect:

Rule Number	Type	Tagline
4729:5-6-01	New	Definitions - nuclear pharmacies and radiopharmaceuticals.
4729:5-6-02	New	Applicability.
4729:5-6-03	New	Preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals.
4729:5-6-04	New	Record keeping.

Important Reminders

Licensees should be aware of the following:

- These rules require compliance with USP 825. A free version of the USP 825 can be downloaded by visiting: <https://go.usp.org/l/323321/2020-03-09/3125jw>
- These rules apply to the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals for humans and animals **prepared by an Ohio pharmacy, including a pharmacy within an institutional facility**. These standards apply to all radiopharmaceuticals prepared by a pharmacy,

including those with radionuclides that emit a single photon, a positron, or a therapeutic particle, and intravascular radioactive devices (e.g. radioactive microspheres).

- These rules **do not apply** to prescribers engaged in the preparation, preparation with minor deviation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals. **NOTE:** Prescribers are required to comply with [Chapter 3701:1-58](#) of the Administrative Code.
- These rules replace the following radiopharmaceutical rules:

Rule Number	Type	Tagline
4729-15-01	Rescind	Definitions.
4729-15-02	Rescind	Responsibility for nuclear pharmacy.
4729-15-03	Rescind	Minimum standards for a nuclear pharmacy.
4729-15-04	Rescind	Labeling of radiopharmaceuticals.
4729-15-05	Rescind	Prohibitions.

For questions regarding radiopharmaceutical preparation standards by Ohio pharmacies, please review the frequently asked questions starting on the next page of this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting:
<http://www.pharmacy.ohio.gov/contact.aspx>.

Q1) Rule 4729:5-6-03 requires compliance with USP 825 for preparation and handling of radiopharmaceuticals. Will the Board begin enforcing USP 825 on February 1, 2022?

Yes. As a reminder, a free version of the USP 825 can be downloaded by visiting:
<https://go.usp.org/l/323321/2020-03-09/3125jw>

Q2) How are radiopharmaceuticals defined?

"Radiopharmaceutical," "radiopharmaceutical preparation," or "radioactive drug" means a finished dosage form of a dangerous drug that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms "radiopharmaceutical" and "radioactive drug" are commonly used interchangeably.

Q3) Are there any exemptions in this rule chapter?

OAC 4729:5-6-02 (C) includes the following exemptions to the requirements of Chapter 4729:5-6:

This chapter does not apply to the preparation, compounding, dispensing, personally furnishing, and repackaging of non-radioactive drugs, including those used as pharmacologic adjuncts for certain nuclear medicine procedures. These drugs shall be prepared in accordance with the applicable provisions of division [4729:7](#) (i.e., traditional pharmacy/prescriber compounding requirements) of the Administrative Code.

- **REMINDER:** These rules **do not apply** to prescribers engaged in the preparation, preparation with minor deviation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals. **NOTE:** Prescribers are required to comply with [Chapter 3701:1-58](#) of the Administrative Code.

Q4) Does the responsible person on an Ohio pharmacy license where radiopharmaceuticals are prepared need to meet certain requirements?

Yes. Except for institutional pharmacies (hospitals, LTC, etc.):

- A nuclear pharmacy shall have an authorized nuclear pharmacist as its responsible person. Responsible person shall also mean the "designated person" as used in USP 825.

INSTITUTIONAL PHARMACY EXCEPTION: For institutional pharmacies (hospitals, LTC, etc.) there is no requirement to have an authorized nuclear pharmacist as the pharmacy's responsible person. However, an institutional facility must comply with the following notification requirements:

An institutional facility licensed as a terminal distributor of dangerous drugs **with an onsite nuclear pharmacy** that is engaged in the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals shall comply with the following:

- Submit notification to the Board, using the [Radiopharmaceutical Notification Form](#), that the facility has a pharmacy that is engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals.

For new facilities, the institutional facility shall notify the Board within ten days of the date an institutional pharmacy engages in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals.

For existing facilities, the institutional facility shall notify the Board within ten days of the effective date of this rule (2/1/2022).

- An institutional facility that ceases to engage in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals shall submit notification to the Board, using the [Radiopharmaceutical Notification Form](#), within ten days of cessation.
- The institutional facility with an on-site nuclear pharmacy shall have a designated person who is an authorized nuclear pharmacist employed by the facility that is responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.
 - For new facilities, the institutional facility shall notify the Board, using the [Radiopharmaceutical Notification Form](#), of the designated person within ten

days of the date the facility engages in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals.

- For existing facilities, the institutional facility shall notify the Board, using the [Radiopharmaceutical Notification Form](#), of the designated person within ten days of the effective date of this rule (2/1/2022).
- If there is a change in the designated person, the Board shall be notified, using the [Radiopharmaceutical Notification Form](#), within ten days of the effective date of the appointment of the new designated person.

The [Radiopharmaceutical Notification Form](#) can be accessed from the TDDD Licensing page of the Board's website or can be accessed directly here: www.pharmacy.ohio.gov/RADnotify.

Q5) Are there any new notification requirements for Ohio pharmacies preparing radiopharmaceuticals?

Yes. OAC [4729:5-6-03](#) requires an Ohio pharmacy to report any event as a medical event, except for an event that results from patient intervention, to the Ohio Department of Health in accordance with rule [3701:1-58-101](#) of the Ohio Administrative Code.

For more information regarding this submission process, please contact the Ohio Department of Health's [Bureau of Environmental Health and Radiation Protection](#).