

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

- Sections Affected**

R4-23-110	Amend
R4-23-681	Amend
R4-23-682	New Section
R4-23-691	Repeal
- The specific authority for the rulemaking, including both the authorizing statutes (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 32-1901(40) and 32-1904(A)(1) and (2)
Implementing statutes: A.R.S. §§ 32-1904(B)(3) and (4)(a), 32-1929, 32-1930(A)(2), and 32-1931(A), (B), (C), and (D)(4).
- The effective date of the rules:**

July 8, 1997
- A list of all previous notices appearing in the Register addressing the final rule:**

Notice of Rulemaking Docket Opening	1 A.A.R. 392, April 28, 1995
Notice of Proposed Rulemaking	3 A.A.R. 386, February 14, 1997
- The name and address of agency personnel with whom persons may communicate regarding this rule:**

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6. An explanation of the rule, including the agency's reasons for initiating the rule:

This rule was initiated at the request of the Nuclear Pharmacy Committee of the Arizona Pharmacy Association. The Arizona Pharmacy Association represents pharmacies and pharmacists in the state of Arizona. The members of the Nuclear Pharmacy Committee are nuclear pharmacists who work for Syncor International and Medi-Physics Inc., the 2 nuclear pharmacy companies in Arizona. In March of 1995, the Nuclear Pharmacy Committee drafted a proposed nuclear pharmacy rule which was presented to the Board staff. The Board staff worked with the committee to refine the proposal. A draft rule was presented to the Board for comment in the fall of 1995 and again in July 1996. The Governor's Regulatory Review Council staff did a courtesy review in June 1995. This rule is the culmination of that joint effort.

The rule includes new definitions for "authentication of product history", "limited-service nuclear pharmacy", "internal test assessment", "pharmaceutical care", "radiopharmaceutical", "radiopharmaceutical quality assurance", and "radiopharmaceutical services". The existing rules addressing radiopharmaceuticals are found in Sections R4-23-681 and R4-23-691. The new rule keeps Section R4-23-681 with some modifications and repeals Section R4-23-691. A new Section R4-23-682 is created containing new language and revised and updated language from the repealed Section. The rule addresses grammar, format, and style changes necessary under the current Administrative Procedure Act and other necessary language changes to provide a clear, concise, and understandable document.

The rule changes the heading of Section R4-23-681 to read: General Requirements for Limited-service Nuclear Pharmacy. Subsection headings, such as General, Compliance with Other Laws, and Transfer of Drugs are eliminated. Subsection (A) establishes the requirements of an authorized nuclear pharmacist. Subsection (B) becomes an introductory statement and subsections (1) and (2) become subsections (1), (2), and (3). The newly defined word "radiopharmaceuticals" replaces the words "radioactive pharmaceu-

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ticals" throughout the rule. Subsection (B) is deleted because existing rule already prohibits compounding and dispensing of drugs by anyone other than a pharmacist or a pharmacy intern under a pharmacist's immediate supervision. Subsections (C) and (D) receive necessary grammar, style, and format changes. Subsection (E) is deleted because existing rule already addresses the security of drugs. Subsection (F) becomes subsection (E) with necessary grammar, style, and format changes. Subsection (G) is deleted because the contents are now addressed in the policies and procedures specified in the new Section R4-23-682. Subsection (H) is deleted because the requirements are addressed in existing rules.

The heading of the new Section R4-23-682 is Limited-service Nuclear Pharmacy. The language from Section R4-23-691 addressing minimum requirements for area and equipment is updated with necessary grammar, style, and format changes. The equipment requirements are streamlined using the existing requirements of the Arizona Radiation Regulatory Agency instead of listing each item of glassware and supplies. The reference library requirement is changed to reflect the style of existing rules for community and hospital pharmacies. New language in subsections (A) and (B) establishes the requirement for a limited-service nuclear pharmacy permit. Subsection (E) establishes requirements for records of acquisition, inventory, and disposition of radiopharmaceuticals. Subsections (G) and (H) establish specifications for written policies and procedures for pharmacy operation and drug distribution.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards for limited-service nuclear pharmacies. The Board further believes that specific regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists in a dynamic healthcare system.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

8. The summary of the economic, small business, and consumer impact:

This economic, small business, and consumer impact statement for the nuclear pharmacy rule analyzes the costs, savings, and benefits that accrue to the Board of Pharmacy, Secretary of State, pharmacists, technicians, pharmacies, and the public.

With the adoption of the proposed rule, the impact on established Board of Pharmacy procedures, Compliance Officer time, and other inspection-related costs is minimal. The benefits to the Board and its compliance staff are non-quantifiable. The estimated additional cost to the Secretary of State's office is minimal. This additional cost stems from Secretary of State's staff time publishing the rules.

The benefits provided by the proposed rules are non-quantifiable. The rule deals with specialized pharmacies and benefits the Board of Pharmacy by promoting consistent compliance. The rule provides protection of public health and safety while allowing service by a unique method or to a particular population. Arizona pharmacies benefit from a rule specific for the particular area of practice because the rule is concise and compliance standards are crystal clear. Pharmacists benefit from better control of all aspects of pharmacy practice through established written policy and procedure.

Under existing rule, nuclear pharmacies are treated as community pharmacies. The nuclear pharmacy rule establishes nuclear pharmacies as limited-service pharmacies. By becoming limited-service pharmacies, existing nuclear pharmacies will bear the cost of complying with the rules for limited-service pharmacies. R4-23-671(E)(2) requires all limited-service pharmacies to submit a copy of the pharmacy's written policies and procedures to the Board office with the original permit application and R4-23-671(E)(3) requires all limited-service pharmacies to conduct a biennial review and revision of the policies and procedures and submit a copy of any revision to the Board office. The additional cost to limited-service nuclear pharmacies is the cost of copying the policies and procedures which is minimal. All existing nuclear pharmacies in the state already use a written policies and procedures system, so creating these policies and procedures will not be an additional cost.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantive changes in the final rules since the publication of the Notice of Proposed Rulemaking. Minor changes for format and word choice were made to improve the clarity, conciseness, and understandability of the rule at the request of the Governor's Regulatory Review staff.

10. A summary of the principal comments and the agency response to them:

No comments were received.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their location in the rules:

None.

13. Was this rule previously adopted as an emergency rule?

No.

14. The full text of the changes follows:

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TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-681. General Requirements for ~~Limited-service Nuclear Pharmacy Permits for Radioactive Pharmaceuticals~~
R4-23-682. ~~Limited-service Nuclear Pharmacy~~
R4-23-691. ~~Pharmacy Permit for Radioactive Pharmaceuticals~~

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to the definitions set forth in A.R.S. § 32-1901, the following definitions apply to this Chapter.

"Active ingredient" means any component which 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 man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug products in a modified form intended to furnish the specified activity or effect.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"AZPLEX" means Arizona pharmacy law examination.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means a date determined by a pharmacist and placed on a prescription label at the time of dispensing intended to indicate a time beyond which the contents of the prescription are not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low- to moderate-risk agents where there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, Revised June 1987 edition, incorporated herein by reference and on file with the Office of the Secretary of State.

"Class 100 environment" means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, June 15, 1988, edition which included January 28, 1991, changes, incorporated herein by reference and on file with the Office of the Secretary of State.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient intended for use in the manufacture of drugs in dosage form, including those that may not appear in the finished product.

"Correctional facility" has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.

"Cytotoxic" means a pharmaceutical that has the capability of killing living cells

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

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"First-aid stations" means units within a business or industrial organization which are limited to, as the name implies, first-aid treatment of injuries incurred in association with the business function.

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Industrial medical stations" means units where drugs are stored, established within businesses and industrial organizations.

"Internal test assessment" means, but is not limited to, performing quality assurance procedures necessary to ensure the integrity of the test.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding, production, dispensing, and distribution of drugs.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and dispenses a majority of its prescription medications or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Lot" means a batch or any portion of a batch of a drug or in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity

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in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a batch or lot of drug can be determined.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mediated instruction" means learning transmitted via intermediate mechanisms such as audio and/or visual tape telephonic transmission, etc.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"Occupational Medicine" or "Industrial Medicine" means the field of medicine dealing with the medical problems associated with persons employed in any occupation.

"Outpatient" or "Outpatient setting" means a person that receives medical treatment as a result of not being a residential patient in a health care institution, or a location where medical treatment is provided to patients not required to be overnight residents of the facility.

"Patient profile" means a readily retrievable, centrally located information record which contains, but is not limited to: patient demographics, allergies, and medication profile.

"Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes, related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, by identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug which is packaged, ordinarily in frequently prescribed quantities, labeled, in compliance with A.R.S. §§ 32-1967 and 32-1968, for storage and subsequent dispensing by a pharmacist, or pharmacy intern under the supervision of a pharmacist, who at that time verifies that it is properly labeled for the patient.

"Provider pharmacist" means the pharmacist who supplies medication to a long-term care facility and maintains medication profiles.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of any radiopharmaceutical but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the suitability of the potential radiopharmaceuticals for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and the keeping of proper records.

"Radiopharmaceutical services" means the procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs, and includes quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Remodel" means to structurally alter the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long-term care facility.

"Sterile pharmaceutical product" means a dosage form free from living microorganisms.

"Strength" means:

The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis) and/or

The potency, that is, the therapeutic activity of the drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means the pharmacist shall be present, assume legal responsibility, and have personal oversight of activities relating to the acquisition, preparation, distribution, and sale of prescription medications by pharmacy interns or supportive personnel.

"Supplying" is the issuing of one or more doses of a proprietary drug in the original container of a manufacturer for subsequent use by the patient.

"Supportive Personnel" means an individual trained to perform activities related to the preparation and distribution of prescription medications, under the supervision of a pharmacist and consistent with policy and procedures as required in R4-23-403.

"Wholesale distribution" means distribution of drugs to persons other than a consumer or patient but does not include:

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 transfer of prescription drugs by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

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;

The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

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The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means anyone engaged in wholesale distribution of drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5 percent of gross sales.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-681. General Requirements for Limited-service Nuclear Pharmacy Permits for Radioactive Pharmaceuticals

A. To be an authorized nuclear pharmacist, a pharmacist shall:

1. Hold a current pharmacist license issued by the Board; and
2. Be certified as a nuclear pharmacist by:
 - a. The Board of Pharmaceutical Specialties, or
 - b. A similar group recognized by the Arizona State Board of Pharmacy; or
3. Satisfy each of the following requirements:
 - a. Meet minimal standards of training for status as an authorized user of radioactive material, as specified by the Arizona Radiation Regulatory Agency and the United States Nuclear Regulatory Commission;
 - b. Submit certification of completion of a Board-approved nuclear pharmacy training program or other training program recognized by the Arizona Radiation Regulatory Agency, with 200 hours of didactic training in the following areas:
 - i. Radiation physics and instrumentation,
 - ii. Radiation protection,
 - iii. Mathematics pertaining to the use and measurement of radioactivity,
 - iv. Radiation biology, and
 - v. Radiopharmaceutical chemistry;
 - c. Submit evidence of a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist in the following areas:
 - i. Procuring radioactive materials;
 - ii. Compounding radiopharmaceuticals;
 - iii. Performing routine quality control procedures;
 - iv. Dispensing radiopharmaceuticals;
 - v. Distributing radiopharmaceuticals;
 - vi. Implementing basic radiation protection procedures; and
 - vii. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and
 - d. Submit written certification, signed by a preceptor who is an authorized nuclear pharmacist, that the above training was satisfactorily completed.

B.A. General: Radiopharmaceuticals are prescription-only drugs that require specialized techniques in their handling and testing to obtain optimum results and minimize hazards.

1. A person shall not Radioactive pharmaceuticals are prescription-only drugs which require specialized techniques in their handling and testing, in order that optimum results may be obtained and hazards may be minimized. It is unlawful to sell, barter, or otherwise dispose of, or be in possession of any radiopharmaceutical radioactive pharmaceuticals, except under the conditions detailed in A.R.S. § 32-1929. It is unlawful for any person to manu-

facture, compound, sell or dispense any radioactive pharmaceuticals, unless he is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist, in accordance with A.R.S. § 32-1961 and these rules, with the exception of a medical practitioner for administration to his patient as provided in A.R.S. § 32-1921(1), and further provided such medical practitioner is licensed by the Arizona Radiation Regulatory Agency to utilize radioactive pharmaceuticals in compliance with A.R.S. § 30-673. This exception includes a hospital nuclear medicine department or medical practitioner's office that is licensed by the Arizona Radiation Regulatory Agency.

2. A person shall not manufacture, compound, sell, or dispense any radiopharmaceutical, unless the person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist in accordance with A.R.S. § 32-1961 and these rules, with the exception of the following, if the following are licensed by the Arizona Radiation Regulatory Agency to use radiopharmaceuticals in compliance with A.R.S. § 30-673:
 - a. A medical practitioner who administers a radiopharmaceutical to the medical practitioner's patient as provided in A.R.S. § 32-1921(A),
 - b. A hospital nuclear medicine department, and
 - c. A medical practitioner's office.
- 3.2. The Board shall It is the intent of the Board of Pharmacy to cooperate with the Arizona Radiation Regulatory Agency and other interested state and federal agencies, in the enforcement enforcing of these rules for the protection of the public, including exchange of licensing and other information, joint inspections, and other activities where indicated.
- B. Pharmacist requirement: A permittee for radioactive pharmaceuticals shall require that only a pharmacist or a pharmacy intern under his immediate supervision, shall compound and dispense such drugs.
- C. Compliance with other laws: All the laws and regulations of the Arizona Radiation Regulatory Agency and the U.S. Nuclear Regulatory Commission including emergency and safety provisions shall be complied with, in In addition to compliance with all the applicable federal and state laws and rules regulations governing drugs, whether radioactive or not, a limited-service nuclear pharmacy permittee shall comply with all laws and rules of the Arizona Radiation Regulatory Agency and the U.S. Nuclear Regulatory Commission, including emergency and safety provisions.
- D. Arizona Radiation Regulatory Agency requirements: A limited-service nuclear pharmacy permittee shall comply with the education Education, experience, and licensing requirements of the Arizona Radiation Regulatory Agency shall be complied with.
- E. Security: All radioactive substances shall be kept locked and secure from unauthorized personnel.
- E.E. Transfer of drugs: A limited-service nuclear pharmacy permittee Radioactive pharmaceuticals shall not ensure that radiopharmaceuticals are be transferred only to a any person or firm that holds a current Radioactive Materials License issued by the Arizona Radiation Regulatory Agency not licensed or authorized to receive such drugs.
- G. Quality control: A permittee for radioactive pharmaceuticals shall be responsible for the radiopharmaceutical quality control of all drugs, including biologicals, dispensed or manufactured. Radiopharmaceutical quality control includes the carrying out and interpretation of data resulting from chemical, biological and physical tests on potential radioactive pharmaceuticals to determine the suitability for use in humans and

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other animals, including internal test assessment and authentication of product history.

- H. Variations: The space, equipment and supply requirements herein are minimum requirements. The Board may require more than the minimum requirements, and the Board may approve a variation from the minimum requirements, if the Board determines that such variation is in the best interests of the public.

R4-23-682. Limited-service Nuclear Pharmacy

A. Before operating a limited-service nuclear pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, and 32-1931, and A.A.C. R4-23-606.

B. A permit to operate a limited-service nuclear pharmacy shall be issued only to a person who is or employs an authorized nuclear pharmacist and holds a current Arizona Radiation Regulatory Agency Radioactive Materials License. A limited-service nuclear pharmacy permittee that fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License shall be immediately suspended pending revocation by the Board. A limited-service nuclear pharmacy permittee shall have copies of Arizona Radiation Regulatory Agency inspection reports available upon request for Board inspection.

1. A limited-service nuclear pharmacy permittee shall designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall be responsible to the Board:
 - a. For the operations of the pharmacy related to the practice of pharmacy and distribution of drugs and devices;
 - b. For communicating Board directives to the management, pharmacists, interns, and other personnel of the pharmacy; and
 - c. For the pharmacy's compliance with all federal and state pharmacy laws and rules.
2. An authorized nuclear pharmacist shall directly supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs.
3. An authorized nuclear pharmacist shall be present whenever the limited-service nuclear pharmacy is open for business.

C. A limited-service nuclear pharmacy permittee shall ensure that the limited-service nuclear pharmacy complies with the standards for personnel, area, security, sanitation, and general requirements in R4-23-608, R4-23-609, R4-23-610, R4-23-611, and R4-23-671.

1. A limited-service nuclear pharmacy shall contain separate areas for:
 - a. Preparing and dispensing radiopharmaceuticals,
 - b. Receiving and shipping radiopharmaceuticals,
 - c. Storing radiopharmaceuticals, and
 - d. Decaying radioactive waste.
2. The Board may require more than the minimum area in instances where equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice.

D. The pharmacist-in-charge shall designate in writing, by title and specific area, the persons who may have access to particular pharmacy areas.

E. A limited-service nuclear pharmacy permittee shall maintain records of acquisition, inventory, and disposition of radiopharmaceuticals, other radioactive substances, and other drugs in accordance with federal and state statutes and rules.

1. A prescription order, in addition to the requirements in A.R.S. § 32-1968(C) and A.A.C. R4-23-407(A), shall contain:

- a. The date and time of calibration of the radiopharmaceutical.
 - b. The name of the procedure for which the radiopharmaceutical is prescribed, and
 - c. the words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product.
2. The lead container used to store and transport a radiopharmaceutical shall have a label that, in addition to the requirements in A.R.S. § 32-1968(D), includes:
 - a. The date and time of calibration of the radiopharmaceutical.
 - b. The name of the radiopharmaceutical.
 - c. The molybdenum 99 content to USP limits.
 - d. The name of the procedure for which the radiopharmaceutical is prescribed.
 - e. The words "physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product.
 - f. The words "Caution: Radioactive Material", and
 - g. The standard radiation symbol.
 3. The radiopharmaceutical container shall have a label that includes:
 - a. The date and time of calibration of the radiopharmaceutical;
 - b. The name of the patient, recorded before dispensing, if the radiopharmaceutical is therapeutic or for a blood product;
 - c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product;
 - d. The name of the radiopharmaceutical;
 - e. The dose of radiopharmaceutical;
 - f. The serial number;
 - g. The words "Caution: Radioactive Material"; and
 - h. The standard radiation symbol.
- E. The following minimum requirements are in addition to the requirements of the Arizona Radiation Regulatory Agency, the applicable U.S. Nuclear Regulatory Commission regulations, and the applicable regulations of the federal Food and Drug Administration. A limited-service nuclear pharmacy permittee shall provide:
1. In addition to the minimum pharmacy area requirements in R4-23-609:
 - a. An area for the storing, compounding, and dispensing of radiopharmaceuticals completely separate from pharmacy areas for nonradioactive drugs;
 - b. A minimum of 80 sq. ft. for a hot lab and storage area; and
 - c. A minimum of 300 sq. ft. of compounding and dispensing area;
 2. The following equipment:
 - a. Fume hood, approved by the Arizona Radiation Regulatory Agency;
 - b. Laminar flow hood;
 - c. Dose calibrator;
 - d. Refrigerator;
 - e. Prescription balance, Class A, and weights;
 - f. Well scintillation counter;
 - g. Incubator oven;
 - h. Microscope;
 - i. Equipment to produce a typed or mechanically printed label;
 - j. Equipment to produce mechanically printed numbers;

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- k. An assortment of labels, including prescription labels and cautionary and warning labels;
 - l. Glassware necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
 - m. Other equipment necessary for radiopharmaceutical quality control for products compounded or dispensed as required by the Arizona Radiation Regulatory Agency;
 - n. Current antidote and drug interaction information; and
 - o. Regional poison control phone number prominently displayed in the pharmacy area;
 - 3. Supplies necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
 - 4. A professional reference library consisting of a minimum of 1 current reference or text addressing each of the following subject areas:
 - a. Therapeutics,
 - b. Nuclear pharmacy practice, and
 - c. Imaging;
 - 5. Current editions and supplements of:
 - a. A.R.S. §§ 30-651 through 30-696 pertaining to the Arizona Radiation Regulatory Agency,
 - b. Rules of the Arizona Radiation Regulatory Agency,
 - c. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,
 - d. Arizona Pharmacy Act and rules,
 - e. Arizona Uniform Controlled Substances Act, and
 - f. Radiological Health Handbook.
 - G. The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare and implement written policies and procedures for pharmacy operations and drug distribution.
 - H. The written policies and procedures of a limited-service nuclear pharmacy shall include the following:
 - 1. Prescription orders;
 - 2. Clinical services and drug utilization management including:
 - a. Drug utilization reviews,
 - b. Inventory audits,
 - c. Patient outcome monitoring,
 - d. Drug information, and
 - e. Education of pharmacy and other health professionals;
 - 3. Duties and qualifications of professional and support staff;
 - 4. Radioactive material handling, storage, and disposal;
 - 5. Drug product procurement;
 - 6. Drug compounding, dispensing, and storage;
 - 7. Investigational drugs and their protocols;
 - 8. Patient profiles;
 - 9. Quality management procedures for:
 - a. Adverse drug reaction reports;
 - b. Drug recall;
 - c. Expired and beyond-use-date drugs;
 - d. Medication or dispensing errors;
 - e. Radiopharmaceutical quality assurance;
 - f. Radiological health and safety;
 - g. Drug storage and disposition; and
 - h. Education of professional staff, support staff, and patients;
 - 10. Recordkeeping;
 - 11. Sanitation;
 - 12. Security;
 - 13. Drug delivery requirements for:
 - a. Transportation,
 - b. Security,
 - c. Radiological health and safety procedures,
 - d. Temperature and other environmental controls, and
 - e. Emergency provisions; and
 - 14. Patient education.
- R4-23-691. Pharmacy Permit for Radioactive Pharmaceuticals**
- A. Minimum requirements:** The following minimum requirements shall be met for a community pharmacy or hospital pharmacy compounding and dispensing radioactive pharmaceuticals. These requirements are in addition to the minimum requirement for space and equipment for other types of pharmacies and the requirements of the Arizona Radiation Regulatory Agency and the applicable U.S. Nuclear Regulatory Commission regulations, and the applicable regulations of the federal Food and Drug Administration. The Board may, if requested, waive rules pertaining to pharmacy permits for non-radioactive drugs for requirements that do not pertain to the practice of nuclear pharmacy.
- 1. **Space:**
 - a. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs.
 - b. Hot lab and storage area shall be a minimum of 80 sq.-ft.
 - c. Compounding and dispensing area shall be a minimum of 300 sq.-ft.
 - 2. **Equipment:**
 - a. Fume hood, approved by the Arizona Radiation Regulatory Agency,
 - b. Laminar flow hood,
 - c. Dose calibrator,
 - d. Refrigerator,
 - e. Electronic balance, or access to one,
 - f. Drawing station,
 - g. **Glassware:**
 - i. 6 beakers 50 ml,
 - ii. 6 beakers 150 ml,
 - iii. 2 beakers 500 ml,
 - iv. 8 volumetric flasks 50 ml,
 - v. 12 volumetric flasks 100 ml,
 - vi. 4 graduated cylinders 10 ml,
 - vii. 4 graduated cylinders 100 ml;
 - h. Well scintillation counter,
 - i. Incubator oven,
 - j. Autoclave,
 - k. Pyrogen oven,
 - l. Microscope,
 - m. Other equipment necessary for radiopharmaceutical quality control for products compounded or dispensed as required by the Arizona Radiation Regulatory Agency.
 - 3. **Supplies:**
 - a. Disposable syringes 1, 3 and 5 cc,
 - b. Multidose vials 10, 20 and 30 cc,
 - c. Disposable alcohol swabs,
 - d. Disposable gloves,
 - e. Appropriate labels for radioactive drugs,
 - f. Other supplies necessary for drugs to be compounded and dispensed
 - 4. **Current references:**
 - a. A.R.S. §§ 30-651 through 30-696 pertaining to the Arizona Radiation Regulatory Agency,
 - b. Rules of the Arizona Radiation Regulatory Agency,

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- c. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,
 - d. United States Pharmacopeia and National Formulary, or Remington, or United States Dispensatory, the latest edition and supplements,
 - e. American Hospital Formulary Service,
 - f. Arizona Pharmacy Act and Rules,
 - g. Arizona Narcotic Act,
 - h. Radiological Health Handbook.
- B. Education and experience: In addition to that required by the Arizona Radiation Regulatory Agency, a pharmacy permittee for radioactive pharmaceuticals shall present to the Board certification from an accredited college of pharmacy that the pharmacist-in-charge for the radioactive pharmaceuticals has completed 90 or more clock hours of formal academic training in nuclear pharmacy and certification he has completed a minimum of three months' on-the-job training under a program approved by the Board.
- C. Supplying of radioactive drugs to medical practitioners: A nuclear pharmacy may furnish radioactive drugs in single or multiple dose containers labeled "for physician use only" in addition to other labeling requirements for radioactive drugs, to medical practitioners who are licensed by the Arizona Radiation Regulatory Agency upon receipt of an order giving the date, address and name of practitioner, and name and amount of radioactivity ordered.