MEETING NOTICE

Missouri Board of Pharmacy
Nuclear Pharmacy Working Group
CONFERENCE CALL

NOVEMBER 28, 2018
2:00 P.M.

Notice is hereby given that the Board of Pharmacy’s Nuclear Pharmacy Working Group will be meeting at 2:00 p.m. on November 28, 2018 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 2:00 p.m. on November 28, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy/Nuclear Working group is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

A tentative agenda for this meeting is attached.
TENTATIVE AGENDA
Missouri Board of Pharmacy
Nuclear Pharmacy Working Group

CONFERENCE CALL
NOVEMBER 28, 2018
2:00 P.M.

1. Welcome & Introductions

2. Approval of Minutes

3. Board Updates
   a. 20 CSR 2220-2.200 (Sterile Compounding)
   b. Practice Guide
   c. USP Chapter 797 & 825

4. 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation) & Potential Rule Changes

5. Future Agenda Topics/Meetings

6. Adjournment
20 CSR 2220-2.500 Nuclear Pharmacy- Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies and the preparation, labeling, dispensing or delivering of compounded radiopharmaceuticals pursuant to a prescription drug or medication order. This regulation is intended to supplement other regulations of the Board of Pharmacy, as well as those of other state and/or federal agencies.

(1) Definitions.

(A) “Address of Use” means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored as defined by 10 CFR 35.2 or a temporary job site for providing mobile nuclear medicine services in accordance with 10 CFR 35.80.

(B) “Agreement State” means any state that has entered into an agreement under subsection 274b of the Atomic Energy Act of 1954, as amended, in which the United States Nuclear Regulatory Commission has relinquished to such states the majority of its regulatory authority over source material, by-product, and special nuclear material in quantities not sufficient to form a critical mass.

(C) “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.

(D) “Authorized nuclear pharmacist” means a pharmacist who holds a current license issued by the board and who is either certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, has attained status as an authorized nuclear pharmacist or an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or Agreement State regulations, including, but not limited to, 10 CFR 35.55, 35.57 and 35.59.

(E) “Contingency Prescription Drug Order” means a radioactive prescription drug order issued for contingency material for a diagnostic purpose.

(F) “Controlled Access Area” means an area outside of the restricted area but inside the pharmacy, access to which will be limited to the public.

(G) “Practice of nuclear pharmacy” means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(H) “NRC” means the United States Nuclear Regulatory Commission.

(I) “Nuclear pharmacy” means the location that provides radiopharmaceutical services and where radiopharmaceuticals and chemicals within the classification of legend drugs, are compounded, dispensed, stored, sold or used for nuclear medicine procedures. The term “nuclear pharmacy” does not include the nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed to patients under the supervision of a licensed physician, authorized by the Nuclear Regulatory Commission or Agreement State regulations.

(J) “Nuclear pharmacy technician” means a person who assists a pharmacist in the practice of nuclear pharmacy who:

(1) Is currently registered as a pharmacy technician with the Board of Pharmacy;

(2) Works under the direct supervision of a nuclear pharmacist; and

(3) (i) has successfully completed a nuclear pharmacy technician training program
provided by an accredited college program or an equivalent company sponsored program approved by the Board, or

(ii) is listed as an “Authorized User of Radioactive Materials” on a nuclear pharmacy's United States Nuclear Regulatory Commission or Agreement State license, provided the nuclear pharmacy is licensed by the Board or in another state.

(iv) For purposes of this rule, a nuclear pharmacy technician does not include assisting personnel not engaged in preparing or compounding medication provided such person does not otherwise assist in the practice of pharmacy.

(K) “Preparing” of radiopharmaceuticals means the addition of a radioactive substance, or the use of a radioactive substance in preparation of a single-dose or multiple-dose medication, pursuant to the prescription of an authorized practitioner for a patient who is being treated by the practitioner. Such preparing of radiopharmaceuticals includes, but is not limited to, loading and eluting of radionuclide generators, using manufactured reagent kits to prepare radiopharmaceuticals, preparing reagent kits, aliquoting reagents and conducting quality control tests of radiochemicals which are to be used as radiopharmaceuticals. Appropriate safety and containment techniques for compounding radiopharmaceuticals shall be used in conjunction with the aseptic techniques required for sterile preparations.

(L) “Prescription Drug Order” means a radioactive prescription drug order issued for a specific patient for a diagnostic or therapeutic purpose.

(M) “Quality control testing” means, but not limited to, the performance of appropriate chemical, biological, physical, radiochemical, and radionuclidic purity tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(N) “Quality assurance procedures” means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(O) “Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles 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 “radiopharmaceutical” also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(P) “Radiopharmaceutical services” means, but not limited to, the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, delivery, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review, and also includes quality assurance procedures, radiological healthcare activities, any consulting activities associated with the use of radiopharmaceuticals, and any other activities required for provision of radiopharmaceutical care; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(Q) “Restricted Area” means an area within the pharmacy that is secured from the Controlled Access Area and to which access is limited for the purpose of protecting individuals
against exposure to radiation and radioactive materials.

(R) “Temporary job site” means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

(S) “Therapeutic Prescription Drug Order” means a radioactive prescription drug order issued for a specific patient for a therapeutic purpose.

(T) “Transport Container” means a container meeting DOT Type A requirements.

(U) “Unit dose container” (e.g., shield or “pig”) means a container designed to hold doses of radiopharmaceutical agents and to prevent or minimize/reduce the emission of radiation or radioactive materials by using appropriate shielding materials.

(2) General Requirements for Pharmacists/Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, compound, dispense, transfer, dispose or manufacture for sale or resale any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission or applicable Agreement State.

(B) For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive regulations that do not pertain to the practice of nuclear pharmacy.

(C) Nuclear Pharmacies shall post, in a conspicuous area of the pharmacy, a copy of the current registration with the Board of Pharmacy and a copy of the most current U.S. NRC or applicable Agreement State license which details a listing of its authorized nuclear pharmacists, and/or a copy, of a reference to its specific location within the pharmacy.

(D) A Nuclear Pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radiopharmaceutical before the radioactive drug is permitted to be dispensed to that facility. The radiopharmaceutical may only be delivered to the authorized addresses or locations listed in, or temporary job sites as authorized by, the NRC/Agreement State license. The authorized physician ordering radiopharmaceuticals is hereby recognized as the patient’s authorized designee for delivery purposes. This regulation is an exemption for Class E permit holders to 20 CSR 2220-2.013 Prescription Requirements, which details authorized delivery sites.

(E) Nuclear pharmacies shall comply with any applicable requirements of other governing agencies regarding its daily operations and the disposal of any biohazardous medical waste.

(F) Any reusable unit dose container that is returned shall be considered to be contaminated. No pharmacy shall utilize a reusable unit dose container for radioactive doses without either an effective process to decontaminate the container of biohazardous substances or an effective mechanism to avoid contamination of the container. No pharmacy may reuse a unit dose container that remains contaminated with blood or other biohazardous substances.

(G) Appropriately labeled and, when required shielded, disposal containers shall be used for radioactive waste and biohazardous from the preparation or the return of radiopharmaceuticals. Disposal of biohazardous waste shall comply with all applicable local, state and federal requirements.

(H) Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission or Agreement State to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, unless the laboratory is engaged in the commercial sale or resale of
radiopharmaceuticals.

(I) A Class E pharmacy may accept returns as authorized by the NRC/Agreement State regulations.

(3) Permits. Any pharmacy providing radiopharmaceutical services must obtain a Class-E radiopharmaceutical permit from the Board.

(A) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, an authorized nuclear pharmacist. All personnel performing tasks in the preparation and dispensing of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of an authorized nuclear pharmacist. The pharmacist-in-charge shall be an authorized nuclear pharmacist and be responsible for all operations of the pharmacy.

(B) The permit to operate a nuclear pharmacy is effective so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Agreement State radioactive materials license. Copies of all regulatory inspection reports shall be made available upon request to the board for inspection.

(C) The nuclear pharmacist-in-charge shall notify the Board of Pharmacy by letter of the outcome of any hearings under state or federal laws or regulations governing radioactive materials involving or against the pharmacy location licensed by the Board. Notification must be within thirty days of the date of the outcome.

(4) Space, Security, Record Keeping and Equipment.

(A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services provided and as required by the Nuclear Regulatory Commission or Agreement State radioactive materials license or as required by 20 CSR 2220-2.200 Sterile Compounding, 20 CSR 2220-2.400 Compounding Standards of Practice or other applicable rules of the Board. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

1. Radiopharmaceutical nonsterile and sterile preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.

(B) The nuclear pharmacy restricted area shall be secured against unauthorized personnel and must be totally enclosed and lockable.

(C) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy, and Nuclear Regulatory Commission or Agreement State.

(D) Nuclear pharmacies shall prepare and dispense radiopharmaceuticals in accordance with accepted standards of nuclear pharmacy practice.

(5) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall be dispensed only to a practitioner or facility authorized by the Nuclear Regulatory Commission or an Agreement State to possess, use and administer such drug for patient use, provided that a radiopharmaceutical may be transferred to a
person who is authorized to possess and use the drug for nonclinical applications in accordance with the regulations of the NRC/Agreement State and the occasional transfer of bulk quantities of radiopharmaceuticals to other authorized persons to meet shortages. A
radiopharmaceutical shall not be dispensed directly to a patient.

(B) The amount of radioactivity shall be determined by dose calibrator, appropriate radiometric methods or decay calculation methods for each individual dose immediately prior to dispensing.

(C) Radiopharmaceuticals are to be dispensed only upon a non-refillable prescription order from a practitioner or facility authorized by the Nuclear Regulatory Commission or Agreement State to possess, use and administer radiopharmaceuticals or the practitioner’s/facility’s designated agent. The prescription order/contingency prescription drug order must be taken by an authorized nuclear pharmacist, intern pharmacist, pharmacy technician. Only pharmacists may receive verbal therapeutic prescription drug orders. The prescription record shall contain all information as required in 20 CSR 2220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and
2. The patient’s name for therapeutic prescription drug orders and blood-containing products.

(D) The labeling requirements in subsection (E) shall not apply to outer transport containers.

(E) The unit dose container of a radiopharmaceutical to be dispensed shall be labeled with—

1. The name and address of the pharmacy;
2. The name and address of the authorized prescriber/facility where the prescription order is to be administered;
3. The date of dispensing and a unique readily retrievable identifier;
4. The standard radiation symbol;
5. The words “Caution Radioactive Material”;
6. The name of the procedure, if known;
7. The name or generally recognized and accepted abbreviation of the radiopharmaceutical, radionuclide and chemical form;
8. The requested amount of radioactivity at the calibration date and time;
9. The radiopharmaceutical beyond-use date;
10. The quantity dispensed;
11. If applicable, Molybdenum-99 content to United States Pharmacopoeia (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and
12. The patient name or the words “Physician’s Use Only” or “Per Physician’s Order” or similar wording in the absence of a patient name. When the prescription is for a therapeutic or blood-containing radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable within a reasonable amount of time from the physician upon demand.

(F) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with—:

1. The standard radiation symbol;
2. The words “Caution Radioactive Material”;
3. The identity of the radiopharmaceutical;
4. The unique readily retrievable identifier of the radiopharmaceutical; and
5. The patient’s name, if known or the words “Physician’s Use Only” or “Per Physician’s Order” or similar wording in the absence of a patient name.

(G) Radioactive drugs. Radiopharmaceuticals approved by the United States Food and Drug Administration are not subject to the unit dose container labeling requirements in subsection (E) or the radiometric measurement requirements of this rule if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the original manufacturer product packaging/labeling.

(6) Reference Manuals. Each nuclear pharmacy shall have a current copy of, or electronic access to:
(A) Applicable reference materials commensurate with the scope of services provided required by 20 CSR 2220.2010 and 20 CSR 2220-2.200;
(B) A current print or electronic edition of statutes and rules governing the pharmacy’s practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;
(C) Agreement State and/or NRC regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material, including but not limited to Title and Title 49 of the United States Code of Federal Regulations.

(7) Special Conditions: Not finalized.
(A) To comply with NRC exposure guidelines of keeping radiation exposure as low as reasonably achievable (ALARA), an alternate means of pharmacist inspection/verification of the final product/preparation may be used [if a pharmacist has previously verified the correct ingredients, calculations, prescription drug order information and label have been prepared or selected for use prior to preparation]. Alternate means may include, but are not limited to, the use of standardized operation protocols, radiation measurement devices, bar-coding technology, or software that requires pharmacist intervention for any action outside of protocols.

OTHER ISSUES TO BE ADDRESSED:
• Required amendments to the sterile compounding rule (need to address things like in-use time vs. beyond-use-date, aseptic technique when moving in and out of the compounding area, staging, hand sanitation)