MEETING NOTICE

Missouri Board of Pharmacy
Nuclear Pharmacy Working Group

June 20, 2018
Governor’s Office Building
200 Madison Street, Room 460
Jefferson City, MO 65109
9:00 a.m.

The Missouri Board of Pharmacy has convened a Nuclear Pharmacy Working Group to review Missouri’s regulation of nuclear pharmacy. Notice is hereby given that the Nuclear Pharmacy Working Group will be meeting at 9:00 a.m. on June 20, 2018. A tentative agenda is attached. If any member of the public wishes to attend, s/he should be present at the Governor’s Office Building, 200 Madison Street, Room 460, Jefferson City, Missouri at 9:00 a.m. on June 20, 2018.

The Working Group may go into closed session at any time during the meeting pursuant to § 610.021.(1) for purposes of legal advice. 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

June 20, 2018
Governor’s Office Building
200 Madison Street, Room 460
Jefferson City, MO 65109
9:00 a.m.

1. Welcome & Introductions

2. Approval of Minutes
   a. 11-15-17
   b. 2-28-18

3. 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation) & Potential Rule Changes
   a. Current Rule
   b. Working Group Proposed Changes (2-28-18)

4. 20 CSR 2220-2.200 (Sterile Compounding) Emergency Rule

5. Beyond-Use Dates/In-Use Times for Nuclear Pharmacy

6. Final Product Verification/Labeling

7. ISO-8 Buffer Areas & Nuclear Pharmacies

8. Proposed 20 CSR 2220-2.010 (Pharmacy Standards of Operation)

9. Future Agenda Topics/Meetings

6. Adjournment
The Missouri Board of Pharmacy’s Nuclear Pharmacy Working Group met in open session during the times and dates stated in the following minutes. The meeting was called to order by Vice-President Douglas Lang at approximately 9:01 a.m. on November 15, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President
Douglas Lang, R.Ph, Vice-President

**Attendees Present**
Samuel Leveritt (Cardinal Health)
Brent McHugh (Mid-America Isotopes)
Carey Unthank (Triad Isotopes)
Richard Van Sant (PharmaLogic)

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Katie DeBold, Inspector
Christa Nilges, Senior Office Support Assistant

VICE-PRESIDENT DOUGLAS LANG CALLED THE MEETING TO ORDER AT 9:01 A.M.

**ITEM # 2 Overview/Discussion of Working Group Purpose/Goals**

**DISCUSSION:** Vice-President Douglas Lang welcomed attendees and introductions were made. Mr. Lang reported the Board asked the Working Group to review Missouri’s regulation of nuclear pharmacy and provide any suggested recommendations/rule changes. Mr. Lang asked for additional input on how proposed USP Chapter 825 may impact Missouri licensees. The following comments were received:

- Samuel Leveritt suggested revising the Board’s nuclear and sterile compounding rules to eliminate inconsistencies. For example, Mr. Leveritt noted the certification requirement for primary engineering controls (PECs) is different in each rule. Mr. Leveritt stated consistency is particularly important given nuclear pharmacies are also licensed as sterile compounders. Mr. Leveritt further suggested the Board address the
use of generator systems that are typically not in ISO-5 areas but may be in a nearby buffer area.

- Brent McHugh suggested the Board review other sterile compounding requirements that may be inappropriate for nuclear such as restrictions applicable to the hood. Specifically, Mr. McHugh noted nuclear pharmacies may need to have certain items in or on the hood such as syringes, tungsten shields and/or non-shedding drapes that are needed for spills. Mr. McHugh noted syringe shields may violate first air but they are essential in nuclear pharmacy.

- Carey Unthank and Brent McHugh reported a critical issue is the Board’s interpretation of in-use/beyond-use times for nuclear ingredients; Samuel Leveritt agreed and noted the Board’s interpretation has significantly impacted nuclear pharmacy.

Douglas Lang suggested the Working Group review the current nuclear rule to identify inconsistencies and needed revisions; Working Group discussion held on 20 CSR 2220-2.500 (Nuclear Pharmacy-Minimum Standards for Operation). A summary of the Working Group’s recommendations are attached in Exhibit A. Members recommended the Board proceed with rule revisions and not wait for USP Chapter 825.

The following additional discussion was held regarding the six (6) hour in-use time for single dose vials/containers and pharmacy bulk vials/containers used in compounding as specified in 20 CSR 2220-2.200(9)(D):

- Samuel Leveritt and Brent McHugh indicated the Board’s enforcement of 20 CSR 2220-2.200(9)(D) is unreasonable and detrimentally impacting nuclear pharmacy by limiting ingredients to a 6-hour in-use time. Mr. Leveritt noted the requirement is not only costly but does not take into account nuclear operations or current stability data.
- Mr. Leveritt noted the in-use time and beyond-use date are essentially synonymous for nuclear pharmacy and noted most radiopharmaceuticals are used within 12-18 hours. Working Group Attendees reported many of the pharmacies have stability studies to show ingredients are still viable after the 6-hour period and questioned if the restriction was truly evidence based.

Further Working Group discussion held; Working Group consensus to research other state requirements and to provide any supporting testing/data to the Board office.

ITEM #6-7 Future Agenda Topics/Meeting dates

DISCUSSION: Working Group consensus to discuss the following agenda items at the next meeting:

- 20 CSR 2220-2.500 suggested changes
- In-Use Time/Beyond-Use Dating
- Nuclear inspection issues. Staff was asked to provide a list of most common nuclear inspection issues.

Member consensus to survey available meeting dates on a Wednesday in January 2018.
MOTION TO ADJOURN
The Working Group adjourned by consensus at approximately 2:00 p.m.

___________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
20 CSR 2220-2.500 Nuclear Pharmacy—Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies, a specialty of pharmacy practice and the preparation, labeling and distribution 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 CSR 35.80.
   (B) “Adult” means an individual 18 or more years of age.
   (C) “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.
   (D) “Area of use” means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using or storing byproduct material.
   (E) “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.
   (F) “Controlled Area” means an area outside of the restricted area but inside the pharmacy, access to which will be limited to the public.
   (G) The “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) The term “nuclear pharmacy” means the location that provides radiopharmaceutical services and where radioactive drugs, and chemicals 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 and/or the Missouri Department of Health.
“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 that 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 formulating and conducting quality assurance 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 preparing sterile product preparations.

An “qualified 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 by agencies of states that maintain certification agreements with the Nuclear Regulatory Commission Agreement State regulations/10 CFR 35.55, 35.57 and 35.59.

“Nuclear pharmacy technician” means a person 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.

“Radiopharmaceutical services” means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, 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 health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical 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.

“Quality control testing” means the performance of appropriate chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.
“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.

“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.

“Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons 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.

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

“Unit dose transport container” means a container designed to transport doses of radiopharmaceutical agents and prevent or minimize/reduce the emission of radiation or radioactive materials during the process by using appropriate shielding materials. Such containers shall include: an effective tamper-evident seal or on the outer container, an effective mechanism to avoid radioactive contamination; and an effective system to prevent contamination of the transport container with blood, bodily fluids, or other biohazardous substances. Biohazardous prevention systems containing a barrier that if used properly eliminates or substantially reduces the potential for contamination of the unit dose transport container, would meet the requirements of these regulations.

General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, compound or dispense any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission and/or the Missouri Department of Health. The requirements of this rule are in addition to and not in substitution of other applicable statutes and regulations administered by the State Board of Pharmacy or the Missouri Department of Health.

(B) Nothing in this rule shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when the use of radiopharmaceuticals is limited to the diagnosis and treatment of patients under the supervision of the physician.

(C) Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health 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.
(D) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a pharmacist or to have a nuclear pharmacy license for radiopharmaceutical preparation and distribution to patients within that institution.

(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 must retain verification of each practitioner’s/institution’s NRC or Agreement State license demonstrating the practitioner/institution is licensed to handle and receive radiopharmaceuticals.

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

(E) Current detailed floor plans or proposed remodeled plans shall be submitted to the State Board of Pharmacy and NRC/Agreement State before approval of the license.

(F) 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.

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

(H) No pharmacy shall utilize a reusable unit dose transport container for radioactive doses without either an effective process to decontaminate the transport container of biohazardous substances or an effective mechanism to avoid contamination of the transport container. No pharmacy shall reuse a unit dose transport container that remains contaminated with blood or other biohazardous substances. Any unit dose transport...
container that is returned with any tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.

(I) Appropriate labeled and shielded disposal containers shall be used for radioactive waste from the preparation of radiopharmaceuticals. Appropriate labeled disposal containers shall be used for biohazardous waste generated from patient cell labeling procedures or returned syringes. Disposal of biohazardous waste shall comply with all applicable local, state and federal requirements.

(J) All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operation efficiency shall be maintained for at least three years.

(K) Nothing in this rule shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when the use of radiopharmaceuticals is limited to the diagnosis and treatment of patients under the supervision of the physician.

(L) 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.

(M) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission or Agreement State to handle radioactive materials, to obtain the services of a pharmacist or to have a nuclear pharmacy license for radiopharmaceutical preparation and distribution to patients within that institution.

(N) A Class E pharmacy may accept returns as authorized by the NRC/Agreement State regulations. The pharmacy shall be required to implement decontamination procedures or disposable liners to prevent biohazard cross-contamination.

(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, a qualified authorized nuclear pharmacist. All personnel performing tasks in the preparation and dispensing of radiopharmaceuticals and ancillary drugs shall be under the direct immediate personal supervision of a qualified authorized nuclear pharmacist, who shall be in personal attendance. 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 only so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Missouri Department of Health Agreement State radioactive materials license. Copies of inspection reports shall be made available upon request to the board for inspection.
(C) Any nuclear pharmacy which provides (transfers) product outside of a patient-specific prescription service must be licensed as a drug distributor in order to provide a product for a prescriber’s use.

(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. 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 required and provided and as required by the Nuclear Regulatory Commission or Agreement State radioactive materials license or as required by 20 CSR 2220-2.200, 20 CSR 2220-2.400 or other applicable rules of the Board. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:
1. Radiopharmaceutical preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.
(B) The nuclear pharmacy professional service 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, Nuclear Regulatory Commission and/or Missouri Department of Health statutes and regulations.
(D) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The State Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards of purity and quality.
(E) A nuclear pharmacy shall have available the following resources:
1. A vertical laminar airflow hood that is annually certified every six (6) months to assure aseptic conditions within the working areas;
2. A sanitary work area that is designed to avoid outside traffic and outside airflow and that is ventilated so that it does not interfere with sanitary conditions. The sanitary work area shall not be used for bulk storage of supplies or other materials;
3. A sink located nearby that is suitable for cleaning purposes;
4. A current policy and procedure manual that includes the following subjects:
   A. Sanitation;
   B. Storage;
   C. Dispensing;
   D. Labeling;
   E. Record keeping;

Comment [GK6]: Sam was going to work on revised definitions for these sections and remove the proposed references to a “secure” area given all of these areas would be secured.
F. Recall procedures;
G. Responsibilities and duties of supportive personnel;
H. Training and education in aseptic technique; and
I. Compounding procedures.

(5) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall be dispensed only to a licensed physician practitioner or facility authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health to possess, use and administer such drug for patient use. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed physician. A radiopharmaceutical shall not be dispensed directly to a patient. Except 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.

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

(C) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a licensed physician practitioner or facility authorized by the Nuclear Regulatory Commission to possess, use and administer radiopharmaceuticals or the physician’s designated agent. Upon receiving an oral prescription order for a radiopharmaceutical or blood product, the nuclear pharmacy shall immediately have the prescription order reduced to writing or recorded in a data processing system. The prescription order must be taken by an authorized nuclear pharmacist, intern pharmacist, nuclear medicine technologistpharmacy technician or designated agents. Nuclear medicine technologists may only receive prescription orders for diagnostic therapeutic radiopharmaceuticals and blood products; and all such prescriptions must be reviewed and initialed by the pharmacist. The prescription record shall contain all information as required in 4 CSR 220-2.01820 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 name of the procedure patient’s name.

(D) A nuclear pharmacy shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical chemical purity.

(E) The labeling requirements in subsection (F) shall not apply to outer DOT Type A transport containers.

(F) The immediate outer unit dose transport container shield 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 is to be administered;

3. The date of dispensing and a unique readily retrievable identifier;

4. The serial number assigned to the order for the radiopharmaceutical;

5. The standard radiation symbol;

6. The words “Caution Radioactive Material”;

7. The name of the procedure, if known;

8. The name or generally recognized and accepted abbreviation of the radiopharmaceutical radionuclide and chemical form;

9. The requested amount of radioactivity and at the calibration date and time;

10. The radiopharmaceutical beyond-use date and in-use time;

11. If a liquid, the volume;

12. If a solid, the number of items or weight;

13. If a gas, the number of ampules or vials;

14. 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

15. 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-product pharmaceutical, 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.

(D)(G) 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; and

4. The serial number or unique readily retrievable identifier of the radiopharmaceutical; and

5. The patient’s name, if known.

(E) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator’s protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter) and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(H) Nuclear pharmacies may dispense United States Food and Drug Administration approved radioactive drugs if the nuclear pharmacy does not process the radioactive drugs in any manner or violate the original manufacturer product packaging/labeling. Drugs dispensed in this manner are not subject to the unit dose transport container labeling requirements in subsection (F) or the radiometric measurement requirements of this rule.
(6) Reference Manuals.

(A) Each nuclear pharmacy shall have a copy of the Missouri Pharmacy Practice Act and current regulations under the act, one recognized text in nuclear pharmacy, and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material reference materials as required by 20 CSR 2220-2.010 and 20 CSR 2220-2.020 and a current copy of or electronic access to Agreement State and/or NRC regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material or electronic access to same, including but not limited to Title 10 CFR FDA Regulations and Title 49 CFR DOT Regulations.

(7) Any preparation of Positron Emission Tomographic (PET) radiopharmaceuticals shall comply with 4 CSR 220-2.200 Sterile Pharmaceuticals and with applicable USP standards.

(7) Special Conditions:

(A) To comply with NRC exposure guidelines of keeping radiation exposure ALARA (as low as reasonably achievable) and 20 CSR 2220-2.200 Sterile Compounding (14) End-Preparation Evaluation (A) Risk Level 1: final preparation inspection, an alternate means of inspection may be used. Alternate means may include, but are not limited to, the use of standardized operation protocols, radiation measurement devices, bar-coding technology, and software that requires pharmacist intervention for any action outside of protocols.

(B) As a Class E pharmacy is not open to the public, rules pertaining to public requirements, including but not limited to signage, counseling, etc. shall not apply. For nuclear pharmacies handling exclusively radiopharmaceuticals, the Board may waive regulations that do not pertain to the practice of nuclear pharmacy.

(C) As a Class E pharmacy only provides radiopharmaceuticals to licensed authorized users for administration to patients, as defined by NRC/Agreement State regulations, rules pertaining to Compounding for Office Use shall not apply. The physician licensed to order radiopharmaceuticals is recognized as the patients authorized designated user.

(D) As a Class E pharmacy is required by NRC/Agreement State regulations to accept returns of potentially biohazardous sharps in reusable unit dose transport containers, the pharmacy shall be required to implement decontamination procedures or disposable liners to prevent biohazard cross-contamination.

(E) Radiopharmaceuticals may only be delivered to the authorized address(es) or location(s) 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.

OTHER ISSUES TO BE ADDRESSED:

- Required amendments to the sterile compounding rule (need to address things like aseptic technique when moving in and out of the compounding area, staging, hand sanitation)
AUTHORITY: sections 338.210, 338.240, 338.250, 338.280, 338.330(3), RSMo 1994 and
338.220 and 338.350, RSMo Supp. 1997.* This rule originally filed as 4 CSR 220-

1997; 338.240, RSMo 1951; 338.250, RSMo 1951, amended 1990; 338.280, RSMo 1951,
The Missouri Board of Pharmacy’s Nuclear Pharmacy Working Group met in open session during the times and dates stated in the following minutes. The meeting was called to order by Vice-President Douglas Lang at approximately 9:10 a.m. on February 28, 2018. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Douglas Lang, R.Ph, Vice-President

**Working Group Members Present**
Samuel Leveritt (Cardinal Health)
Brent McHugh (Mid-America Isotopes)
Carey Unthank (Triad Isotopes)
Richard Van Sant (PharmaLogic)

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Christa Nilges, Senior Office Support Assistant

**Public Attendees**
Michael Roberts (Sofie Biosciences)

**VICE-PRESIDENT DOUGLAS LANG CALLED THE MEETING TO ORDER AT 9:10 A.M.**

**ITEM # 1 Welcome & Introductions**

**DISCUSSION:** Douglas Lang welcomed attendees and reported Executive Director Kimberly Grinston was attending a legislative budget hearing and would join the meeting at a later time.

**ITEM # 3 Beyond-Use Dates/In-Use Times for Nuclear Pharmacy**

**DISCUSSION:** Samuel Leveritt presented information regarding in-use times/beyond-use dates for common radiopharmaceuticals and provided a comparison of 20 CSR 2220-2.200(9)(D) to USP Chapter 797. Working Group members commented the six (6) hour in-use time for single dose vials/containers and pharmacy bulk vials/containers in 20 CSR 2220-2.200(9)(D) is
inappropriate for nuclear pharmacy given stability data and current nuclear practice. Attendees reviewed supporting documents from industry groups and noted most radiopharmaceuticals are used within 12-18 hours limiting the possibility of growth. Attendees noted this is an issue of patient safety/access to care and agreed to provide draft rule language to the Board.

ITEM # 2  20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation)

DISCUSSION: Working Group members reviewed suggested rule changes from the 11-15-17 meeting; A summary of the Working Group’s recommendations are included in Exhibit A.

ITEM # 4  Product Labeling for the Preparation of Radiopharmaceuticals

DISCUSSION: Attendees reported a pharmacist may not review the final product or label prior to dispensing/distribution due to the nature of nuclear pharmacy. Attendees advised final product verification may be unsafe/hazardous. Staff asked if a pharmacist pre-verifies ingredients or label information before compounding; Attendees reported this depends on the nature of the operation but noted many pharmacies require some form of pharmacist pre-verification. Attendees noted technology is also used to ensure the preparation falls within acceptable ranges and reported technicians usually compound only one preparation at a time reducing the risk of error. Brent McHugh further noted most radiopharmaceuticals are diagnostic and will not physically harm patients. Further Working Group discussion held; Consensus to amend rule to allow alternative verification options (e.g., use of technology/a dose calibrator).

ITEM #6-7  Future Agenda Topics/Meeting dates

DISCUSSION: Working Group consensus to discuss the following agenda items at the next meeting:

- 20 CSR 2220-2.500 suggested changes
- In-use time/Beyond-use dating
- ISO-8 buffer areas for nuclear pharmacy
- Compliance issues between in-house policy manuals and BOP rule
- Rule exemptions in proposed 20 CSR 2220-2.010 relating to required references, posted signage and final product verification

Member consensus to survey future meeting date availability.

ADJOURNMENT
The Working Group adjourned by consensus at approximately 3:01 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
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) “Adult” means an individual 18 or more years of age.

(C) “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.

(D) “Area of use” means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using or storing byproduct material.

(E) “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.

(F) “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.

(G) “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.

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

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

(J) The “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.

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

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

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) A nuclear pharmacy technician does not include individuals engaged in delivering radiopharmaceuticals provided he/she does not otherwise assist a pharmacist in the practice of pharmacy.

“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 that 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 assurance 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.

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

“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.

“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.
“Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons 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.

“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, health physics, 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.

“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.

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

“Therapeutic Prescription Drug Order” means a radioactive prescription drug order issued for a specific patient for blood products or for a therapeutic purpose.

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

“Unit dose container” (e.g., shield or “pig”) means a container designed for hold doses of radiopharmaceutical agents and to prevent or minimize/reduce the emission of radiation or radioactive materials by using appropriate shielding materials. Such container shall include an effective mechanism to prevent contamination of the container with biohazardous 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 or 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. Any container that is returned shall be considered to be contaminated.

(G) Appropriately labeled and, when required shielded, disposal containers shall be used for radioactive waste and biohazardous waste from the preparation or the return of radiopharmaceuticals. Appropriately labeled disposal containers shall be used for biohazardous waste generated from patient cell labeling procedures or returned syringes. 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) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission or Agreement State to handle radioactive materials, to obtain the services of a pharmacist or to have a pharmacy license for radiopharmaceutical preparation, distribution and delivery to patients within that institution. I would suggest striking this entire paragraph because it isn’t needed given the Bd’s limited jurisdiction over hospitals or removing the physician language since we don’t have authority to require bd certification.

(J) 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) Radioactive drugs 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 or designated agents. Only
pharmacists may receive verbal therapeutic prescription drug orders for therapeutic-
radiopharmaceuticals and blood products. The prescription record shall contain all information as required in 20 CSR 2220-
2020 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 radiopharmaceutical prescription drug
orders and blood-containing products.

(D) The labeling requirements in subsection (E) shall not apply to outer United States
Department of Transportation Type A 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
radioactive 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 product 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 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 required by 20 CSR 2220.2010 and 20 CSR 2220-
2.200; and
(B) 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 10
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)

AUTHORITY: sections 338.210, 338.240, 338.250, 338.280, 338.330(3), RSMo 1994 and
338.220 and 338.350, RSMo Supp. 1997.* This rule originally filed as 4 CSR 220-
**20 CSR 2220-2.010 Pharmacy Standards of Operation**

PURPOSE: This rule establishes general operational standards for pharmacies licensed by the Board.

(1) Pharmacy Staff and Supervision. All Board licensed pharmacies must be under the supervision of a pharmacist-in-charge who has been designated with the Board and holds a current and active Missouri pharmacist license. For pharmacies located outside of Missouri, the designated pharmacist-in-charge must hold a current and active pharmacist license in the state where the pharmacy is located.

   (A) In the event the pharmacist-in-charge designated with the Board changes, the pharmacy may not continue operations until a new pharmacist-in-charge is named. A change of pharmacist-in-charge application must be submitted to the Board with the applicable fee within fifteen (15) calendar days after a new pharmacist-in-charge is designated.

   (B) A controlled substance inventory must be taken at or immediately prior to a pharmacist-in-charge change as required by 20 CSR 2220-2.090.

   (C) All Board licensees and registrants must wear an identification badge or similar identifying article that identifies their name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist).

(2) Required Equipment. Pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the *United States Pharmacopoeia* (USP) or *Remington’s Pharmaceutical Sciences*. Additionally, pharmacies must have a manual system/device or other equipment for numbering or uniquely identifying prescriptions/medication orders along with appropriate equipment for producing prescription/medication order labels.

(3) Reference Materials. The following references/resources must be physically maintained or immediately accessible in electronic form at the pharmacy:

   (A) 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;
(B) Generally recognized reference(s) or other peer-reviewed resource(s) that include the following items/topics:

1. All drugs approved by the United States Federal Drug Administration (FDA); and
2. Pharmacology of drugs;
3. Dosages and clinical effects of drugs; and
4. Patient information and counseling.

(4) General Standards of Operation. Board-licensed pharmacies shall comply with all applicable state and federal law governing pharmacy practice and medication handling, disposal and distribution. Except as otherwise provided by law or Board rule, pharmacies must ensure:

(A) All Missouri and federal pharmacy licenses, permits or registrations are current and accurate, including, the pharmacy’s name, permit classification(s) and address;
(B) Individuals practicing or assisting in the practice of pharmacy are appropriately licensed or registered with the Board and are appropriately trained for the duties performed;
(C) All pharmacy, pharmacist, intern and pharmacy technician licenses/registrations are conspicuously posted with a photo attached that is not smaller than two by two inches (2” x 2”). Alternatively, licenses and registrations with the required photo may be maintained in a central location within the pharmacy, provided the licenses/registrations are immediately retrievable during an inspection or available to the public if requested;
(E) Medication and drug-related devices are properly and accurately prepared, packaged, dispensed, distributed and labeled under clean, and when required, aseptic conditions. Staff required to touch individual dosage units (e.g., tablets, capsules, etc.) must wear disposable gloves;
(F) The pharmacy is maintained in a clean and sanitary condition and trash is disposed of in a timely manner. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law;
(G) Appropriate sewage disposal and a hot and cold water supply are available within the pharmacy, except as otherwise provided by the Board. The required water supply may not be located within a bathroom;
(H) The pharmacy is free from insects, vermin and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA); and
A pharmacist shall not fill or refill any prescription or medication order which was written more than one (1) year before being presented to the pharmacist.

(5) Drug Storage. Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the *United States Pharmacopeia* (USP).

(A) Temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that are reviewed at least once daily.

(B) No outdated, misbranded or adulterated drugs or devices may be dispensed or maintained within the pharmacy’s active inventory, including prescription and related nonprescription items. Outdated, misbranded or adulterated medication and medication for personal employee use must be quarantined in an area that is clearly identified and physically separate from medication maintained for dispensing, distribution or other pharmacy use. Drugs for the personal use of pharmacy staff or personnel must be labeled in accordance with section 338.059, RSMo, or as otherwise required by law.

(C) Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from medication and medication-related devices. Open food or beverages used in compounding or intended for patient use with medication may be stored in the same area as drugs and drug-related devices as long as the items are separated from other inventory and sanitary conditions are maintained at all times.

(D) Medication may not be stored on the floor.

(E) Appropriate lighting, ventilation and humidity must be maintained in areas where drugs are stored and dispensed.

(6) Security. Adequate security and locking mechanisms must be maintained to prevent unauthorized pharmacy access and to ensure the safety and integrity of drugs and confidential records. Pharmacy traffic must be restricted to authorized persons so that proper control over drugs and confidential records can be maintained at all times.
(A) If the pharmacy is located in a facility that is accessible to the public and the pharmacy’s hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings or other openings that would allow unauthorized access into the pharmacy are not allowed.

(B) Pharmacies dispensing or stocking controlled substances must comply with all federal and state controlled substance security requirements.

(C) In addition to the other requirements of this subsection, a Class-I pharmacy within a residence must be located in a physically separate room that has a door with a suitable lock. Patients are not allowed in a Class-I pharmacy located within a residence. Other than a Class-I pharmacy, no pharmacy permit will be issued to any location that is located in a residence regardless of zoning.

(7) Record Keeping. Pharmacy records must be accurately maintained in compliance with applicable state and federal law. Records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for inspection, photographing or duplication by a Board representative. Unless otherwise provided by law, records required by Chapter 338 or 20 CSR 2220 that do not have a specified retention time must be kept for two (2) years and readily retrievable at the request of the Board or the Board’s authorized designee.

(A) Each pharmacy shall designate either a primary manual or electronic record keeping system which will be used to record the dispensing of all prescriptions and medication orders. Poison sales may be recorded in a separate manual log. Except as otherwise authorized or required by law, at least three (3) separate files of prescriptions/medication orders must be maintained:

1. A separate file for Schedule I and II controlled substances;
2. A separate file for Schedules III, IV and V controlled substances; and
3. A separate file(s) for all other prescriptions/medication orders.

(B) Distribution records. Unless otherwise authorized by law or the Board, pharmacies shall maintain inventories and records of all legend drugs received and distributed that include:

1. The date of the transaction/distribution;
2. Product name, strength and quantity;
3. The names of the parties;
4. The sender’s address or, for drugs distributed by the pharmacy, the receiver’s address; and
5. Any other information required by state or federal law.

(8) Offsite storage. Medication or patient records may be maintained at a facility located at a separate address or premises from the pharmacy provided the facility is registered with the Board prior to use. Registration notices must be submitted on a form approved by the Board and include the address of the facility and hours of operation (if applicable).

(A) Adequate security and storage conditions must be maintained at these facilities to guarantee the security and integrity of records, medication and drug-related devices. At a minimum, registered storage facilities must maintain a functioning alarm system. Any breach in security must be documented and reported to the Board electronically or in writing within fifteen (15) days of the breach.

(B) Storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and will be subject to inspection by the board pursuant to section 338.150, RSMo.

(C) No record less than two (2) years old may be stored offsite. Patient records stored at an offsite facility must be retrievable within two (2) business days of a request from the board or its authorized designees.

(D) No fee will be charged by the board for registering a storage facility under this subsection.

(9) Mandatory Reporting. Pharmacies must notify the board in writing or electronically within fifteen (15) days of any final disciplinary action taken against a Board licensee or registrant for conduct that might have led to disciplinary action under § 338.055, RSMo, or resignation of a licensee/registrant in lieu of such final disciplinary action. The notification must include:

(A) The pharmacy’s name and permit number;
(B) Name of person making the notification;
(C) The licensee’s or registrant’s name and license/registration number;
(D) Date of action;
(E) Reason for action; and
(F) Any additional information required by law.

(10) Drug samples shall not be maintained in or dispensed by pharmacies, except as otherwise authorized by state and federal law, including, but not limited to, 21 U.S.C. section 353 and the federal Prescription Drug Marketing Act of 1987.

(11) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The following prescription drugs may be possessed by a home health or hospice agency identified in this section without a pharmacy license or permit:

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine, epinephrine and methylprednisolone;
5. Vaccines; and
6. Tuberculin test material.

(B) The agency shall have policies and procedures that address at least the following:

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving orders from an authorized prescriber for drug administration;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for storing and transporting drugs by the agency and nurse; and
6. Quantity of drugs possessed by the agency and nurse.

(C) The nurse must have authorization from an authorized prescriber, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) Up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient provided the patient or the patient’s representative has been instructed verbally or in writing on how to perform the procedure. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient’s medical record. Drugs left with the patient may not be returned to the agency.
(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer’s storage requirements. Except as otherwise authorized by section (5)(C) of this rule, refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to the amount necessary to meet the needs of the agency’s patient population for two (2) weeks.

(12) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy that an employee, has violated pharmacy law or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(13) Exemptions. At its discretion, the Board may grant an exemption to the facility requirements of this rule for a time period designated by the Board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length and proposed procedures or safeguards for protecting the public safety, health or welfare if the exemption is approved.