Louisiana Board of Pharmacy
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Blueprint for Inspection of Pharmacies

Module IV – Nuclear Pharmacy Services

General Pharmacy

001.00 Is the Pharmacist-in-Charge (PIC) or pharmacy manager/director present for the inspection?

002.00 Are photographs allowed during the inspection?

General Operations & Licensure

003.00 Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc.) posted?

004.00 Is the Radiation Safety Officer (RSO) the same as is listed on the Radioactive Materials (RAM) license?

005.00 Is the PIC an Authorized User (AU) on the RAM license? List all Aus.

006.00 Is the most recent board of pharmacy inspection report available for review?

006.01 Were any deficiencies noted?

007.00 Is the most recent Nuclear Regulatory Commission (NRC) or Dept. of Environmental Quality (DEQ) inspection report available for review?

007.01 Were any deficiencies noted?

008.00 Has this pharmacy been inspected by any other state for which it holds a license?

009.00 Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

010.00 Is the pharmacy operating under a variance or waiver granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

011.00 Has the pharmacy been inspected or visited by the DEA?

012.00 Has the pharmacy been inspected by the FDA?

013.00 Has the pharmacy been inspected by the Environmental Protection Agency (EPA), Department of Transportation (DOT), or any other outside agency?

014.00 Does the pharmacy hold any accreditations or certifications?

015.00 Has the pharmacy held any accreditations or certifications in the past that they no longer hold?

016.00 Were any deficiencies detected on the last internal audit?

017.00 Does this pharmacy handle investigational drug (IND) radiopharmaceuticals?

018.00 Does the pharmacy ***distribute*** compounded preparations to practitioners for "office use" or "physician use"?

019.00 Does the pharmacy ***distribute*** compounded preparations to hospitals, clinics, or surgery centers?

020.00 When the pharmacy ***delivers*** or ***distributes*** pharmaceuticals, does the pharmacy maintain a copy of each customer's current RAM license/registration?

021.00 Does the pharmacy provide compounded preparations to other pharmacies for dispensing?

022.00 Does the pharmacy purchase any compounded preparations from other entities for dispensing to patients?

023.00 Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?

023.01 If yes, products are verified as appearing on the Drug Shortage List in effect under Sec. 506E of the Federal Act at the time of compounding, distribution and dispensing.

023.02 If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing.

024.00 ***Nonsterile Compounding:*** Does the pharmacy compound oral preparations (capsules, liquids, etc.)?

025.00 ***Sterile Compounding:*** Does the pharmacy compound parenteral preparations?

026.00 ***Sterile Compounding:*** Does the pharmacy compound parenteral suspensions?

027.00 ***Sterile Compounding***: Does the pharmacy compound inhalation preparations?

028.00 Does the pharmacy perform testing in-house (such as purity, radiochemical purity, potency, sterility, endotoxin, environmental monitoring)?

029.00 Does the pharmacy send samples to an outside lab to perform testing?

Policy & Management

030.00 Policies and procedures (P&P) for the program are maintained in the pharmacy in an immediately retrievable form.

031.00 Do the P&Ps include the prescription processing, compounding, dispensing, delivery, receipt and storage, and the handling of hazardous drugs, and handling infectious waste and spills?

032.00 Are the P&Ps reviewed and updated regularly?

033.00 Are systems in place for the ongoing monitoring of state and federal laws and rules for changes in those laws or rules?

034.00 Is there a statement in the P&P, or are other means used, that the most stringent laws or rules are followed?

035.00 Does the pharmacy maintain all required records, including but not limited to prescription files and invoices, on site?

036.00 Does the pharmacy have access to appropriate law references, including state and federal regulations, including for those states in which the pharmacy is licensed, as well as the NRC?

037.00 Does the pharmacy have access to appropriate dosage and toxicology references?

038.00 Does the pharmacy have access to appropriate practice-specific references (nuclear, geriatric, pediatric, etc.)?

039.00 Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?

040.00 Does the pharmacy have a hazardous waste handling and collection system?

Quality Assurance / Quality Improvement (QA/QI)

041.00 Is there a documented continuous quality improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing Quality

Related Events (QREs)?

042.00 Is QA data kept on site?

043.00 Are quality self-audits performed?

044.00 Is Quality Related Event (QRE) defined?

044.01 Is there a form to fill out for a QRE?

044.02 Reporting: Incidents of QREs are reported to a nationally-recognized error reporting program, an outside peer review committee, or a patient safety organization.

045.00 Are external errors documented and tracked?

046.00 Are internal errors documented and tracked?

047.00 Are complaints documented, tracked, and investigated as appropriate and the information is used as part of the CQI program?

048.00 Are reports of contamination or instability of compounded preparations documented, investigated, and tracked, and is there a recall system in place?

049.00 Does the pharmacy CQI program include viable environmental monitoring?

049.01 Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded, including a recall system.

049.02 Are deficiencies in compounding, labeling, packaging, and quality testing and inspection identified and corrected?

050.00 Are pharmacy information systems and technology performance issues measured and tracked?

051.00 Are any other measurements tracked and analyzed?

052.00 QRE data collected is analyzed to assess causes and any contributing factors (root cause).

053.00 Is data trended over time, e.g., against previous years' data?

054.00 Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

055.00 Have process or policy changes or improvements been made based upon other data collected in the QA/QI program?

056.00 Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.

Animal Compounding Compliance

057.00 The compounding meets the same standards as compounding for human patients.

058.00 The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.

059.00 For therapy doses, the pharmacy obtains appropriate information to assess correct dosage such as animal species, breed, or weight.

060.00 It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.

061.00 The facility has a list of drugs and components not allowed when compounding for food-producing animals.

062.00 The pharmacist is familiar with, or has a reference regarding, drug residues in the food chain and withdrawal times if compounding for food-producing animals.

063.00 The pharmacist is familiar with, or has a reference regarding, regulations for drug use in performance animals, e.g., race or show horses, racing dogs, etc.

Personnel Information

064.00 Is there a process for periodic verification of validity of personnel licenses (registrations)?

065.00 Are all personnel wearing name tags that clearly identify if they are a pharmacist , intern, or technician?

066.00 If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, the training and certifications are verified.

067.00 Does the pharmacy have Visiting Authorized Nuclear Pharmacists?

067.01 Do the visiting nuclear pharmacists have written authorizations on file?

067.02 Are the visiting nuclear pharmacists' licenses on file in the pharmacy?

067.03 Are visiting nuclear pharmacists limited to 60 days per year or less?

067.04 Are all records associated with the visiting nuclear pharmacist maintained for at least 5 years after the last visit?

068.00 Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?

069.00 Does the pharmacy maintain the proper technician to pharmacist ratio?

070.00 Do employees undergo background checks upon hire?

071.00 Do employees undergo drug testing upon hire?

072.00 Is new hire training, including orientation, general pharmacy procedures, HIPAA, Radiation Safety/ALARA [as low as reasonably achievable], Occupational Safety & Health Administration (OSHA) blood borne pathogen, and hazardous materials handling performed and documented?

073.00 Is ongoing annual training performed and documented, including topics such as HIPAA, Radiation Safety/ALARA, OSHA blood borne pathogen, or HAZCOM (OSHA's Hazard Communication Program)?

074.00 Is there a performance review process and is it documented?

075.00 Is a procedure for corrective or disciplinary action in place and documented?

Personnel Compliance

076.00 Have all personnel of reproductive capacity who handle or compound radiopharmaceuticals / radioactive materials confirmed in writing they understand the risk of handling radiopharmaceuticals / radioactive materials?

077.00 Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks) who may have contact with radiopharmaceuticals / radioactive materials on handling the spills associated with them?

078.00 Personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly / efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas).

079.00 Personnel demonstrate knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination, including reporting.

080.00 ***Nonsterile Compounding:*** There is documentation that the training includes cleaning and disinfection, garb, and manipulation of ingredients, including quality testing, labeling, and RAM handling.

081.00 ***Nonsterile Compounding:*** There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before trainee is allowed to perform compounding independently.

082.00 ***Nonsterile Compounding:*** There is documentation that training includes the operation of any equipment that may be used when preparing compounded products.

083.00 ***Nonsterile Compounding:*** There is documentation that employees performing nonsterile compounding are evaluated at least annually on compounding competency, including compounding technique, equipment, and materials handling.

084.00 ***Sterile Compounding:*** There is documentation that all compounding personnel have passed initial and subsequent annual written exams that include QA procedures for the appropriate compounding risk levels including RAM.

085.00 ***Sterile Compounding:*** There is documentation that all compounding personnel have passed initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling RAM.

086.00 ***Sterile Compounding:*** There is documentation that new compounding personnel have passed initial observed gowning procedures and three gloved fingertip sampling tests.

087.00 ***Sterile Compounding:*** There is documentation that compounding personnel preparing low or medium risk level preparations have passed an annual observed gowning procedure and gloved fingertip sampling test.

088.00 ***Sterile Compounding:*** There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk level preparations.

089.00 ***Sterile Compounding:*** The media fill testing procedures include:

089.01 Media selection, including obtaining Certificates of Analysis or growth promotion certification from suppliers;

089.02 Fill volume;

089.03 Incubation time and temperature;

089.04 Inspection of filled units;

089.05 Documentation;

089.06 Interpretation of results; and

089.07 Action levels set with the corrective actions required.

090.00 ***High-Risk Sterile Compounding:*** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six months.

091.00 ***High-Risk Sterile Compounding:*** There is documentation that a media fill test procedure is performed for each compounding employee at least every six months.

092.00 ***Sterile and Nonsterile Compounding:*** Are all personnel that perform cleaning activities in the compounding areas appropriately trained, including housekeeping or other outside personnel if used for cleaning?

Facility & Security

093.00 Is entry to prescription product storage and processing areas limited to task-critical employees?

094.00 Is entry into the compounding areas limited to task-critical employees, i.e., pharmacists and other trained and authorized pharmacy personnel?

095.00 Are drugs secured to prevent unauthorized removal or access?

096.00 Does the pharmacy have a working security / alarm system in place?

097.00 Does the pharmacy have cameras?

098.00 Does anyone have access to the pharmacy after hours in the absence of the pharmacist?

099.00 Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break? If so, is there a policy regarding what activities may or may

not be allowed during the pharmacist's absence?

100.00 Is the "Notice to Workers" [required by NRC] posted?

101.00 Is the "Notice to Employees [NRC Form 3] posted?

102.00 If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.

103.00 Is the blood compounding area separate and distinct from the general compounding area?

103.01 Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding area)?

104.00 Are chemicals stored in the appropriate manner, e.g., per SDS?

105.00 Are all volatile products, e.g., Xe-133 gas, liquid I-131 NaI, stored and manipulated in a negative pressure environment?

105.01 If the pharmacy handles radioactive gases, are the clearance time and safety procedures posted?

106.00 Are there housekeeping standards to ensure the environment is professional, safe, neat, and clean?

107.00 Is the pharmacy clean and is there appropriate space for the prescription volume?

108.00 Is there a heating and air conditioning system?

109.00 Temperature monitoring is performed in drug storage areas (if separate from the compounding areas) and maintained within 20° to 25° C (68° to 77° F), or more restrictive if warranted by specific drug product storage requirements.

109.01 Temperature monitoring in the drug storage area is performed at least once daily and documented.

109.02 Excursion action plan is in place, including evaluating excursion effects on drug product integrity.

110.00 Humidity monitoring is performed in drug storage areas (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements, generally 35-60%.

110.01 Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max.

110.02 Excursion action plan in place including evaluating excursion effects on drug product integrity.

111.00 Are the refrigerator and freezer restricted to drug products only (no food)?

112.00 Temperature monitoring in the refrigerator is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used.

112.01 Is the temperature in the refrigerator within the USP range (2° to 8° C or 36° to 46° F) or as specified by FDA approved labeling for drug product storage?

113.00 Temperature monitoring in the freezer is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration.

113.01 Is the temperature in the freezer within the USP range (-25° to -10° C or -13° to 14° F) or as specified by FDA approved labeling for drug product storage?

114.00 Are there contingency plans in the event of power outage or refrigerator / freezer failure?

115.00 Are there contingency plans in the event of heating or air conditioning failure?

Environmental Monitoring Compliance

116.00 ***Nonsterile Compounding:*** All PECs (primary engineering controls) have been certified within the last six months.

117.00 ***Sterile Compounding:*** The most recent PEC and room certification report is available.

117.01 All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months.

117.02 All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last six months.

117.03 Certification is performed at least every six months and whenever a

device or room is relocated or altered, or major service to the facility is performed.

117.04 Certification procedures such as those outlined in the Controlled Environmental Testing Association (CETA)'s *"Certification Guide for Sterile Compounding Facilities"* (CAG-003-2006) shall be noted on the report.

117.05 If the certification procedures used are not those outlined in *"Certification Guide for Sterile Compounding Facilities"* (CAG-003-2006), the facility has performed a comparison and determined the procedures used are equivalent or better than the procedures outlined in *"Certification Guide for Sterile Compounding Facilities"* (CAG-003-2006).

117.06 The PIC or compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.

118.00 The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or when next calibration is due).

118.01 The equipment used had not exceeded its calibration date at the time of certification.

119.00 The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.

119.01 ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources.

119.02 ISO Class 8 anteroom is certified as having the recommended minimum of 20 ACPH. {*Recommended}*

119.03 If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.

120.00 Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the hoods and rooms). The smoke flow is described in the report for the various tests as turbulent, sluggish, smooth, etc.

120.01 Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).

120.02 Air pattern analysis was conducted to confirm positive pressure (and negative pressure into required compounding rooms) at all points around all openings, doorways, and pass-throughs.

120.03 Air pattern analysis was conducted around particle generating equipment while the equipment was in operation to confirm airflow.

121.00 Differential air pressure between rooms was measured.

121.01 The differential pressure measured was at least 0.02” water column positive from the clean/buffer room to the anteroom and between the anteroom and all adjacent spaces with the doors closed. [Radioactive licensing may prohibit anteroom from being positive to unrestricted general area.]

121.02 The differential pressure measured was at least 0.01” water column negative from the room containing volatile products to the adjacent room with the doors closed.

122.00 Displacement airflow between rooms or areas was measured; required for a clean/buffer room without a door that closes to the anteroom – may be an open space or may have plastic strips in doorways.

122.01 Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the clean/buffer room to the anteroom.

123.00 Particle counts of particles 0.5 um and larger were measured under dynamic conditions.

123.01 ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).

123.02 ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).

123.03 ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).

124.00 HEPA filter tests were performed.

124.01 All room HEPA filters were leak tested and if leaks found, they were fixed.

124.02 All PEC HEPA filters were leak tested and if leaks found, they were fixed.

125.00 Viable air (every six months) and surface sampling (periodically) tests have been conducted as required.

125.01 PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.

125.02 Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin [TSApl] added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used.

125.03 Viable air sampling by active impaction using a volumetric air sampling device.

125.04 Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom, and the samples contained a sufficient volume of air (400 – 1,000 liters).

125.05 Surface samples performed on all direct compounding areas inside of each ISO Class 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.

125.06 Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive):

Classification	*Air Sample*	*Surface Sample*
ISO Class 5	> 1 CFU/m^3	> 3 CFU/plate
ISO Class 7	> 10 CFU/m^3	> 5 CFU/plate
ISO Class 8	> 100 CFU/m^3	> 100 CFU/plate

125.07 CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level.

125.08 If any highly pathogenic microbes (i.e., mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation (e.g., recleaning and retesting), and conduct investigation into the source(s) of the contamination.

126.00 ***Materials Tests:*** Molybdenum-99 breakthrough tests are performed and records kept for at least 5 years.

Product Ordering, Receipt, and Inventory

127.00 Is the pharmacy restricted to buying prescription drugs from certain distributors or manufacturers?

127.01 If restricted, does the PIC approve the vendors?

128.00 Are all orders received when the pharmacy is open?

129.00 Does the pharmacy purchase any compounded preparations from other entities for dispensing to patients?

130.00 Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder or liquid APIs (active pharmaceutical ingredients) such as I^{131} for capsules or solutions?

130.01 Does the pharmacy verify that the manufacturer / repackager of the API is an FDA-registered facility?

130.02 Does the pharmacy use APIs that are not from an FDA-registered facility?

131.00 Does the computer system track on-hand quantities of products?

132.00 Are orders generated and sent by the computer for prescription products, including controlled substances?

133.00 Does the pharmacy maintain required inventories (such as change in PIC, theft/loss, etc.)?

134.00 Are incidents of diversion or resignation/termination of personnel for cause reported?

135.00 Does the pharmacy have a complete physical inventory of products performed at least once yearly?

136.00 Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft?

137.00 Are all products inspected upon receipt to detect any packaging issues, damage, etc.?

138.00 How are outdated, damaged, or recalled products segregated?

139.00 Are non-RAM expired or damaged products destroyed on site?

Components

140.00 Certificates of Analysis (COAs) are obtained for all bulk APIs (such as I^{131} for making capsules and solutions) and for media used for viable testing.

141.00 Certificates for each sealed source are kept on file.

142.00 USP or NF grade substances are used, if available.

143.00 APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "For Research Purpose Only" or "Not for Drug Use" or "Veterinary Use Only" or are handwritten from other pharmacies.

144.00 All substances and components have a complete label including a batch control or lot number, and an expiration date.

145.00 For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date.

146.00 All APIs are labeled with the date they were received.

147.00 If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration date from the original container).

148.00 Containers are labeled with appropriate OSHA hazard communication labels and are stored correctly.

149.00 Nonsterile Compounding: Is water an ingredient? If so, what type is used?

150.00 Does the pharmacy use nonsterile empty vials and vial stoppers, or closures and terminally sterilize them with an on-site autoclave?

Prescription/Order Processing

151.00 Are any portions of the prescription processing performed at a different location?

152.00 Does the pharmacy obtain a copy or verify the RAM license of the facility to which the radiopharmaceutical will be delivered?

153.00 Does the pharmacy verify the state medical license of the physician identified on the facility RAM license?

154.00 Is there a procedure to follow when a RAM license for the facility or the license of the prescriber cannot be obtained or verified?

155.00 Does the pharmacy have electronic prescription capability?

156.00 Does the pharmacy provide routine maintenance to the pharmacy computer system, and is the information backed up?

157.00 Is there a continuity plan should the system become inoperable?

Patient Profiles and Communication

158.00 Does the patient information gathered include patient contact information, age, date of birth, and gender?

159.00 For therapy doses, does the pharmacy receive appropriate information to assess correct dosage, such as geriatric or pediatric weight-based doses?

160.00 Does the pharmacist perform an evaluation of the dose, safety, and intended use of the preparation to be compounded?

161.00 Does the pharmacy take back prescription drugs from customers?

162.00 Are providers instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?

163.00 Does the after-hours voicemail message have instructions on whom to contact based on urgency of issue?

Patient Confidentiality

164.00 Is the PIC also the HIPAA Privacy Officer?

165.00 Is there a HIPAA policy in place for employees, vendors, and contractors?

166.00 Do employees deemed nonessential to patient care have access to confidential patient information, such as delivery services?

167.00 Is access to the pharmacy system limited to appropriate personnel?

168.00 Are confidential documents shredded?

169.00 Does the pharmacy destroy PHI (personal health information), including labeled prescription vials?

170.00 Does the crisis plan include security of paper and electronic patient information?

Prescription Packaging and Transporting

171.00 Does the pharmacy utilize employee drivers to deliver prescriptions to patients and/or facilities?

172.00 Does the pharmacy utilize other services/carriers to deliver prescriptions to patients and/or facilities?

173.00 There is a tracking system in place to verify delivery of prescription products.

174.00 Deliveries of RAM are directly to a secure location at a healthcare facility.

175.00 Is only authorized packaging used?

175.01 Are DOT-7A performance test records on file for each type of packaging used by the pharmacy?

175.02 Is the packaging tamper-evident?

Equipment

176.00 Appropriate equipment and utensils rae available, clean, and in good working order.

177.00 Appropriate instruments and meters (Geiger-Mueller survey meters, rate meters, Cutie Pie survey meters, etc.) are available, including documentation for use (policies and procedures and operating instructions).

178.00 PEC prefilters are checked and replaced regularly.

179.00 Is all equipment thoroughly cleaned promptly after each use to prevent cross contamination?

180.00 Automated Compounding Devices (ACDs), such as repeater pumps, are used for sterile compounding, and there is a policy and procedure for their calibration and use.

180.01 There is documentation of the ACD tubing being changed or discarded every 24 hours.

180.02 The ACD is used when performing media fill testing.

Nonsterile Compounding – Beyond Use Dating (BUD)

181.00 BUDs are assigned from the day of preparation.

182.00 BUDs are assigned based on dispensing in tight, light-resistant containers / overpacks.

183.00 Extended BUDs are supported by testing data.

184.00 Extended BUDs are assigned and the facility has performed it own stability testing.

185.00 BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of API and not later than six months.

186.00 BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).

187.00 BUDs for water-containing semisolid formulations are not later than 30 days.

Nonsterile Compounding – Environment

188.00 The nonsterile compounding area is a controlled environment and separate from the general pharmacy.

189.00 The pharmacy performs nonsterile compounding in a ventilated cabinet.

190.00 Ventilated cabinets used for nonsterile compounding are certified or tested periodically.

191.00 There is sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.

192.00 Only one preparation is compounded at a time.

193.00 The compounding area is well-lit.

194.00 Appropriate protective attire (gowns, gloves, masks, etc.) is available.

195.00 There is a sink for the nonsterile compounding area with hot and cold potable water, soap or detergent, and air driers or single-use towels.

196.00 ***Temperature*** in the compounding area is maintained to provide controlled room temperature of 20 to 25 C (68 to 77 F), or more restrictive if warranted by specific drug product storage requirements.

196.01 If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max.

196.02 Excursion action plan is in place, including evaluating excursion effects on drug product integrity.

197.00 ***Humidity*** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements, but is ***recommended*** generally in the range of 35-60%.

197.01 Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max.

197.02 Excursion action plan is in place, including evaluating excursion effects on drug product integrity.

198.00 All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.

199.00 All components and packaging containers and closures are properly rotated to use oldest first.

Nonsterile Compounding – Documentation

200.00 The pharmacy creates a Master Formulation Record the first time before compounding a new preparation.

201.00 Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.

202.00 The ***Master Formulation Record*** includes:

202.01 Official or assigned name, strength, and dosage form;

202.02 All necessary calculations;

202.03 Description of all ingredients and their quantities;

202.04 Compatibility and stability information including references (when available);

202.05 Equipment used for the preparation;

202.06 Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors);

202.07 Container used and packaging requirements;

202.08 Assigned BUD information;

202.09 Labeling information, including the name of and quantity or concentration of each active ingredient;

202.10 Description of the finished preparation;

202.11 Storage requirements; and

202.12 Quality control procedures and expected results (e.g., dose measurement of capsule in the dose calibrator).

203.00 The pharmacy creates a Compounding Record for each compound prepared.

204.00 The ***Compounding Record*** includes:

204.01 Official or assigned name, strength, and dosage of the preparation;

204.02 Master Formulation record reference;

204.03 Sources, lot numbers, and expiration dates of all components;

204.04 Total quantity or number of dosage units compounded;

204.05 Person compounding the preparation;

204.06 Person performing the quality control procedures;

204.07 Person who approved the preparation;

204.08 Date of compounding;

204.09 Assigned internal identification number or prescription number;

204.10 Description of the final preparation;

204.11 Assigned BUD;

204.12 Duplicate label;

204.13 Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.); and

204.14 Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver, including investigation and recall, if appropriate.

Nonsterile Compounding – Compounding Procedures

205.00 The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure it is error-free.

206.00 Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality, including a unit-by-unit inspection of the components.

207.00 The containers and closures selected meet USP standards (from container supplier).

208.00 Container selection determined by physical and chemical properties of the preparation.

209.00 Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.

210.00 Personnel don appropriate protective garb when performing compounding.

211.00 Routine compounding procedures for batch preparation completed and verified according to written procedures, including: calculations correct, weighing and measuring performed correctly, order of mixing correct, and compounding techniques performed correctly.

212.00 Procedures for in-process checks followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution, and component usage. ***Recommendation:*** *compounding accuracy checked by a person other than the compounder.*

213.00 There are no deviations from the Master Formulation Record, unless they are approved and deemed appropriate by a pharmacist and a new Master Formulation Record is created.

214.00 There is a procedure for cleaning which is followed, e.g., after each preparation, daily tasks, monthly tasks, etc.

215.00 Personnel are appropriately garbed for protection when cleaning.

Nonsterile Compounding – Release Checks

216.00 The finished preparation is observed to appear as expected in the Master Formulation Record and documented.

217.00 As appropriate, the final completed preparation is assessed for weight, mixing, clarity, color, consistency, pH, and strength/activity, with results documented.

217.01 Batch preparation (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).

217.02 Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated, including appropriate packaging and labeling of hazardous materials.

218.00 The immediate container shall be labeled with:

218.01 The standard radiation symbol;

218.02 The words “Caution – Radioactive Material”;

218.03 The name of the pharmacy; and

218.04 The prescription number.

219.00 Does the labeling on patient-specific containers include?:

219.01 State required prescription label information;

219.02 Identifiers for the person preparing the compound and performing the final verification;

219.03 BUD;

219.04 An indication that this is a compounded preparation; and

219.05 Any additional special handling requirements.

220.00 The immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

220.01 The standard radiation symbol;

220.02 The words “Caution – Radioactive Material”;

220.03 The name of the radionuclide;

220.04 The chemical form;

220.05 The amount of RAM contained, in millicuries (mCi) or microcuries (µCi).

220.06 If the radioactive drug is a liquid, the volume in milliliters; and

220.07 The requested calibration time for the amount of radioactivity contained.

Sterile Compounding – Environment

221.00 The anteroom has a line of demarcation or other separation of the dirty to the clean side.

221.01 Carts used to bring supplies from the storeroom are kept on the outside of the line demarcation.

221.02 Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.

222.00 All surfaces of the sterile preparation compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate count generating.

223.00 Walls are constructed of durable materials, which are cleanable, such as epoxy-coated or heavy-gauge polymer material. If panels are used, they are locked together and sealed.

224.00 The ceiling surface shall be impervious and hydrophobic. If tiles are used, they shall be locked and the seam between the tiles and where they meet the walls shall be caulked and sealed.

225.00 The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with cowing to the sidewall, and a sealed seam where the cowing meets the wall.

226.00 The clean/buffer room or anteroom does not have dust collecting overhangs.

227.00 The exposed surfaces of:

227.01 PEC are free of dirt, rust, chips, and particulate matter;

227.02 Light fixtures are smooth, mounted flush, and sealed.

228.00 A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his hands and is away

from and not adjacent to any PECs.

229.00 There is no sink or drain in the clean/buffer room.

230.00 All air ducts controlling air flow into the sterile compounding area are equipped with HEPA-filtered air that maintains the clean/buffer room with at least an ISO Class 8 environment.

231.00 Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.

232.00 Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.

233.00 If compounding occurs using nonsterile ingredients, products, components, or devices (e.g., compounding with nonsterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.

233.01 Pre-sterilization procedures for high-risk CSPs (compounded sterile preparations) such as weighing and mixing are performed in no worse than an ISO Class 8 environment.

234.00 Does the ISO Class 8 clean room or buffer area door lead into an ISO Class 8 anteroom?

235.00 Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.

235.01 Anteroom is at least 0.02” wc (water column) positive pressure to general pharmacy areas.

235.02 Clean/buffer room is at least 0.02” wc positive pressure to general pharmacy areas.

235.03 Hazardous compounding room and drug storage area is at least 0.01” wc negative pressure to ISO Class 7 anteroom.

235.04 Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device.

235.05 Written plan in place to detect and react to pressure differentials outside of limits.

236.00 If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips – no door that closes), the air flow is measured across the openings.

236.01 The airflow is at least 40 feet per minute across the entire opening.

236.02 Airflow is read and recorded each shift (minimum of once daily) or continuously recorded.

236.03 Written plan in place to detect and react to airflow measurements outside of limits.

236.04 This area is used only for low- and medium-risk compounding – hazardous and high-risk compounding not allowed.

237.00 The doors into the anteroom from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time – by interlocking, training of personnel, or signage.

238.00 The inside and outside doors of a pass-through are prevented from both being open at the same time – by interlocking, training of personnel, or signage.

239.00 ***If the PEC is a BSC or LAFW that is <u>not</u> located in an ISO Class 7 clean/buffer room***, the BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.

239.01 If low risk, do the compounds located in segregated area have BUDs of 12 hours or less?

239.02 All garbing requirements are adhered to.

239.03 PEC is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.

239.04 This location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas.

240.00 ***If the CAI/CACI is not located in an ISO Class 7 clean/buffer room***, the CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions, including transferring of ingredients, components, and devices as well as during preparation of CSPs.

240.01 The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.

240.02 The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.

240.03 The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).

241.00 **Temperature** in the compounding area is maintained to provide controlled room temperature of 20 to 25 C (68 to 77 F), or more restrictive if warranted by specific drug product storage requirements.

241.01 Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Records are maintained.

241.02 Excursion action plan is in place including evaluating excursion effects on drug product integrity.

242.00 ***Humidity*** in the compounding area is maintained to provide humidity in the range warranted by specific drug product storage requirements, with a general ***recommended*** range of 35-60%.

242.01 Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max.

242.02 Excursion action plan is in place including evaluating excursion effects on drug product integrity.

243.00 Are the blowers on PECs operated continuously during compounding activity, including during interruptions of less than eight hours?

244.00 When the ISO Class 5 PEC blower is turned off and before other personnel to perform compounding activities, is only one garbed person allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and sanitizing the work surface?

Sterile Compounding – Cleaning and Disinfection

245.00 Are all personnel performing cleaning appropriately garbed?

246.00 Is the sterile compounding area equipped with appropriate non-shedding cleaning equipment and supplies?

247.00 If cleaning tools are reused, is there a procedure to rinse and sanitize the tools?

248.00 Are reusable tools appropriately labeled to prevent them from being used inappropriately?

249.00 For cleaning and sanitizing agents that are not “ready for use” formulations, are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use, and is the preparation of

cleaning supplies or agents documented?

250.00 Are cleaning and sanitizing agents appropriately labeled including expiration dates?

251.00 Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?

252.00 Is the ISP Class 5 PEC cleaned at the beginning of each shift, between compounding different preparations, at least every 30 minutes while compounding, and after spills or suspected surface contamination?

253.00 Does sanitizing of the ISO Class 5 PEC include sanitizing with sterile 70% IPA (isopropyl alcohol) using a non-linting wipe?

253.01 If heavily soiled, cleaning includes the appropriate agent.

254.00 Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?

255.00 Does daily cleaning include the floors starting from the clean room and working outwards?

256.00 If fatigue mats are used in the clean room or anteroom, are they cleaned daily and left to dry on both sides?

257.00 Is a tacky mat used, and if so, is there a procedure in place regarding replacement?

258.00 Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the PECs thoroughly cleaned monthly?

259.00 Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?

Sterile Compounding – Garbing

260.00 Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.

261.00 Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas.

262.00 Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.

263.00 Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.

264.00 Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).

265.00 Garbing includes head and facial hair covers and masks.

266.00 Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.

267.00 The gown is non-shedding with sleeves that fit snugly around the wrists and enclosed at the neck.

268.00 All bare skin on the arms and legs is covered.

269.00 Prior to donning sterile glove, a waterless alcohol-based surgical hand scrub with persistent activity is used and hands allowed to dry.

270.00 Upon leaving the sterile preparation compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.

271.00 Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes.

272.00 Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing.

Sterile Compounding – Compounding Procedures

273.00 Gloves are disinfected with adequate frequency with an appropriate disinfectant, such as sterile 70% IPA.

274.00 Nonessential objects that shed particles are prohibited in the clean/buffer room area, including pencils, cardboard cartons, paper towels, reading material, and cotton items, e.g., gauze pads.

275.00 Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the clean/buffer room area.

276.00 Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer

wrap as the item is introduced into the aseptic work area) and brought into the clean/buffer room in a bin or on a movable cart.

277.00 Compounding employees are using appropriate aseptic technique.

277.01 If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for the surveyor to observe the compounding process.

278.00 Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.

279.00 All rubber stoppers of vials and bottles and the neck of ampoules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.

280.00 Are opened or needle-punctured single-dose containers (bags, bottles, syringes, or vials) that are opened or punctured in worse than ISO Class 5 air used within one hour and the remaining contents discarded?

281.00 Single-dose vials exposed to ISO Class 5 or cleaner air are used within six hours of the initial puncture and any remaining contents discarded.

282.00 Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.

283.00 The *Compounding Record* is complete with the following minimum data elements:

283.01 Official or assigned name, strength, and dosage of the preparation;

283.02 Names, lot numbers, and expiration dates of all components;

283.03 Total quantity or number of units compounded;

283.04 Person compounding the preparation;

283.05 Person performing the quality control procedures;

283.06 Person who approved the preparation;

283.07 Date of compounding;

283.08 Assigned internal identification number or prescription number;

283.09 Assigned BUD and reference if extended beyond USP guidelines;

283.10 Duplicate label;

283.11 Sterilization method (if applicable); and

283.12 Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation and recall, if applicable.

284.00 Procedure for in-process checks is followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.

285.00 Labels on ***batch*** preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.

286.00 The immediate container shall be labeled with:

286.01 The standard radiation symbol;

286.02 The words “Caution – Radioactive Material”;

286.03 The name of the pharmacy; and

286.04 The prescription number.

287.00 Labeling on patient-specific containers includes:

287.01 State required prescription label information;

287.02 Identifiers for the person preparing the compound and performing the final verification;

287.03 BUD;

287.04 Route of administration and flow rate (if applicable); and

287.05 Any additional special handling requirements.

288.00 The immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

288.01 The standard radiation symbol;

288.02 The words “Caution – Radioactive Material”;

288.03 The name of the radionuclide;

288.04 The chemical form;

288.05 The amount of RAM contained in millicuries or microcuries;

288.06 If the radioactive drug is a liquid, the volume in milliliters; and

288.07 The requested calibration time for the amount of radioactivity contained.

289.00 All manufacturer-supplied products are stored in original manufacturer containers.

290.00 BUDs assigned that are greater than 12 hours are documented with justification based on USP guidelines, testing, or literature.

291.00 If BUDs are set according to manufacturer package insert recommendations, the products are prepared ***exactly*** according to package insert.

292.00 Appropriate sterilization methods are used and documented.

Sterile Compounding – Release Checks and Tests

293.00 For suspensions, is the particle size measured (where applicable)?

294.00 Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?

295.00 Are there checks for container, closure integrity, and any other apparent visual defects?

296.00 Is compounding accuracy documented by verification of steps?

297.00 Is verification of ingredient identity and quantity verified? Is there a reconciliation of components?

298.00 Are labels verified as being correct, and is a copy of the label included in the record?

299.00 ***Sterility Testing*** complies with USP <71>. If testing is performed to a more stringent standard, describe in inspection notes.

299.01 Sterility testing includes both bacterial and fungal testing.

299.02 Sterility testing is performed on all compounded sterile preparations that have extended BUDs.

299.03 Sterility testing is performed for high-risk compounded sterile preparations prepared in batches of more than 25 identical containers.

299.04 Sterility testing is performed for compounded sterile preparations exposed longer than 12 hours at 2°to 8°C or longer than 6 hours at warmer than 8°C before being sterilized.

299.05 The appropriate quantities of units are sterility tested:

- *For parenterals:*
  - For less than 100 units, test 10% or 4 units, whichever is greater;
  - For 100 to 500 units, test 10 units; and
  - For more than 500 units, test 2% or 20 units, whichever is less.
- *For large-volume parenterals:*
  - 2% of the units or 10 containers, whichever is less.
- *For non-parenterals (eye drops, inhalation, etc.):*
  - For less than 200 units, test 5% or 2 containers, whichever is greater;
  - For 200 or more units, test 10 containers.

299.06 For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken.

299.07 If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber for the patient to whom a potentially contaminated compounded sterile preparation was administered are notified of the potential risk.

300.00 The appropriate quantity of units is used for sterility testing.

301.00 ***Endotoxin Testing*** complies with USP <85>. If testing is performed to a more stringent standard, describe in inspection notes.

301.01 Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages, such as ampoules, bags, syringes, vials, etc.?

301.02 High-risk CSPs prepared in multiple dose vials for administration to multiple patients.

301.03 High-risk CSPs exposed longer than 12 hours at 2° to 8°C (25° to 46°F) or longer than 6 hours at warmer than 8°C (46°F) before they are sterilized.

301.04 For products failing testing, product is quarantined, and an investigation is performed and action taken.

302.00 ***Purity testing:*** CSPs are tested for radioactive purity.

303.00 View a sampling of testing records. Products that have been dispensed or distributed that failed testing (e.g., sterility, endotoxin, or radiochemical purity) have been appropriately recalled and investigated.

Revision History