



CRITERIA FOR INSPECTION FOR CLASS E: RADIOPHARMACEUTICAL PHARMACY
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- Licensed and qualified nuclear pharmacist is on duty or the proper signage is displayed
- Required licenses/registrations are displayed and current
- Outdated or defective legend drugs are separated from inventory
- Drugs stored under appropriate conditions and at required temperatures
- All prescriptions or drug orders are checked by licensed pharmacist on duty
- Correct dispensing and labeling of drug containers as per federal and state laws
- Compliance with DEA order form requirements
- Compliance with annual inventory controlled substance requirements
- Compliance with controlled substance laws and regulations
- Compliance with generic substitution laws
- Compliance with drug distributor laws; Receipt of drugs/devices
- Compliance with drug distributor laws; Transfers of drugs/devices; Recordkeeping
- Proper procedure for the repackaging/prepackaging of drug products
- Proper maintenance of prescription records and records concerning the acquisition and disposition of all radioactive drugs/material
- Pharmacy maintains current policy and procedure manual
- Proper procedures utilized for compounding of drugs
- Adequate areas for dispensing; shipping/receiving; storage; waste decay
- Documentation and correction of any adverse events with radioactive or non-radioactive drugs
- The RAM license is in good standing and is absent of any current citations or disciplinary actions
- Equipment and supplies comply with applicable state and federal laws/regulations governing the safe handling, use, storage, preparation, dispensing, distribution and disposal of radioactive and non-radioactive drugs:
 - Well scintillation counter
 - Chromatographic apparatus
 - Radiation monitoring equipment
 - Syringe and vial shields
 - Decontamination supplies
 - Transport containers
 - Vertical laminar flow hood properly certified
 - Shielding is present to prevent radiation exposure in unrestricted areas of the facility
 - Documentation that ventilation systems from fume hoods and biological cabinets are adequate to prevent the accidental release of airborne radioactive materials inside the facility
 - Instrument maintenance and repair logs are maintained and documentation is available