

West Virginia Board of Pharmacy

1207 Quarrier St., 4th Floor

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Nuclear Pharmacies – Documents to be presented during an Inspection

1. All regulatory licenses/permits/RAM license including list of authorized users
2. Show the Sterile Compounding Policy & Procedure Manual and all required documentation records. 15-1-16.2.2
 - All personnel have passed initial and subsequent annual competency assessments of aseptic (to include didactic with written testing and observational) competency skills including handling of RAM and HD (797)
 - All personnel have passed initial and subsequent annual gloved fingertip testing (797)
 - All personnel have passed initial and subsequent annual media fill testing (797)
 - Certifications of ISO class 7 and 8 secondary engineering controls (every 6 months) per CETA standard CAG 03-2006-13 (797)
 - Certifications of ISO class 5 primary engineering controls (every 6 months) CETA standard CAG 03-2006-13 (797)
 - Viable and non-viable air sampling results (797)
 - Surface sampling results (797)
 - Cleaning records: daily, weekly, monthly (797)
3. Non-Sterile compounding (if performed)
 - Training records
 - Annual competency assessment (didactic with written testing and observational)
 - Master formulation records
 - Compounding records
4. Show the Quality Assurance Program documents including recent staff meeting minutes. 15-1-20.2.3
 - All records related to ambient dose surveys, contamination surveys, molybdenum -99 breakthrough tests, etc.
 - All records required for NRC compliance and inspections
 - Instrument calibration records
 - Quality control measures and documentation
 - Certifications received by staff and/or facility
5. Returned drug log if applicable. 15-1-12.3
6. Records of technician trainee training including hours accrued. 15-7.4.5
7. Show the approved Pharmacy Technician Training Program booklet or folder or other associated training programs 15-7-2.5
8. Record of pharmacist working over 12-hour shift if applicable. 15-1-14.8.1
9. Have a copy of an up-to-date Combined Technician Listing and Confidentiality Affidavit prepared for the inspector. 15-1-20.3.1
15-1-20.3.2.10
10. Please download a copy of the inspection form(s) from the Board website and do a self-evaluation.