## West Virginia Board of Pharmacy

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## Nuclear Pharmacies – Documents to be presented during an Inspection

- 1. All regulatory licenses/permits
- 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
8. Record of pharmacist working over 12-hour shift if applicable.
15-7-2.5
15-1-14.8.1

9. **NABP CE MONITOR REPORT** for all pharmacists regularly employed and floaters assigned to this facility this year.

## Please read the following carefully and comply:

For those licenses renewed in <u>2023: NABP CE Monitor</u> Report from <u>7-1-2021</u> to <u>6/30/2023</u> only! For those licenses renewed in <u>2024: NABP CE Monitor</u> Report from <u>7-1-2022</u> to <u>6/30/2024</u> only!

Records for most current four years CE should be available at employment site at all times; But they will not be reviewed during this inspection.

10. Have a copy of an up-to-date Combined Technician Listing and Confidentiality Affidavit 15-1-20.3.1 prepared for the inspector. 15-1-20.3.2.10