6800.8008 QUALITY ASSURANCE.

Subpart 1. **Quality control program.** There must be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. The end product must be examined on a sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.

Subp. 2. **Hood certification.** All laminar flow hoods must be inspected by a qualified individual for operational efficiency at least every 12 months. Appropriate records of the inspection must be maintained.

Subp. 3. **Prefilters.** Prefilters for the clean air source must be replaced on a regular basis and documented.

Subp. 4. **Bulk compounding.** If bulk compounding of parenteral solutions is performed using nonsterile chemicals, extensive end-product testing must be documented before release of the product from quarantine. The process must include testing for sterility and pyrogens.

Subp. 5. **Expiration dates.** If the product is assigned an expiration date that exceeds seven days from its compounding date, there must be in-house data or data in the literature to assure the sterility and stability of the product when it is used by the patient.

Subp. 6. **Quality control audits.** There must be documentation of quality assurance audits at regular, planned intervals.

Statutory Authority: *MS s 151.06*

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