WAC 246-871-080 Quality assurance. There shall be a documented, ongoing quality assurance program that is reviewed at least annually.

(1) The quality assurance program shall include but not be limited to methods to document:

(a) Medication errors;

(b) Adverse drug reactions;

(c) Patient satisfaction;

(d) Product sterility.

There shall be written documentation that the end product has been tested on a sampling basis for microbial contamination by the employee responsible for compounding parenteral products. Documentation shall be on a quarterly basis at a minimum.

(2) Nonsterile compounding. If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in *Remington*, must be documented prior to the release of the product from quarantine. This process must include appropriate testing for particulate matter and testing for pyrogens.

(3) Expiration dates. There shall be written justification of the chosen expiration dates for compounded parenteral products.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-871-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), § 360-16A-100, filed 1/17/90, effective 2/17/90.]