657—13.3(155A) Responsibilities.

13.3(1) *Pharmacist.* Each pharmacy shall have a pharmacist responsible for ensuring that:

a. Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

b. Appropriate cleanliness conditions are maintained, including preservation of the sterile environment during the compounding process.

c. Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used.

d. Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits.

13.3(2) *In-process checking procedure.* Each pharmacy shall establish a written quality assurance procedure that includes the following in-process checks:

a. Appropriate procedures are followed for measuring, mixing, diluting, purifying, sterilizing, packaging, and labeling of the specific preparation.

b. Packaging selection is appropriate to preserve the sterility and strength of the preparation.

c. All functions performed by nonpharmacists are verified by the pharmacist before the preparation is dispensed to the patient.

13.3(3) *Training documentation.* All personnel involved with compounding, repackaging, or manipulating sterile preparations shall be adequately educated and trained. Training shall include written documentation certifying that compounding personnel are able to adequately complete the following activities:

a. Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces.

b. Select and appropriately don protective garb.

c. Maintain or achieve sterility of preparations in ISO Class 5 primary engineering control devices.

d. Identify, weigh, and measure ingredients.

e. Manipulate sterile products aseptically, sterilize high-risk preparations, and label preparations.

f. Protect personnel and compounding environments from contamination by hazardous drugs.