657—13.31 (155A) Quality assurance (QA). The pharmacy shall establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

13.31(1) *Physical performance QA.* The portion of the quality assurance program that monitors facilities, equipment, and personnel performance shall include, but need not be limited to, the following:

a. Methods for verification of automated compounding devices for parenteral nutrition compounding.

b. Methods for sampling finished preparations to ensure that the pharmacy is capable of consistently preparing sterile preparations that meet appropriate risk level specifications and to ensure product integrity.

c. Procedures for inspection of all prescription orders, written compounding procedures, preparation records, and materials used to compound at all contamination risk levels, to ensure accuracy of ingredients, aseptic mixing, sterilizing, packaging, labeling, and expected physical appearance of the finished preparation.

d. Procedures for visual inspection of preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

e. Procedures for review of all orders and packages of ingredients to ensure that the correct ingredients and quantity of ingredients were compounded.

f. Methods for routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

g. Methods for ensuring personnel qualifications, training, and performance, including periodic performance of applicable MFT procedures.

h. Procedures for visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments.

i. Methods for establishing beyond-use dates of preparations.

13.31(2) *Care outcomes QA.* The portion of the quality assurance program that monitors patient care shall include, but need not be limited to, the following:

a. Utilizing specific procedures for recording, filing, and evaluating reports of adverse events and the quality of preparation identified in the adverse event.

b. Utilizing written policies and procedures that include specific procedures or instructions for receiving, acknowledging, and dating the receipt of products.

c. Reviewing documented patient or caregiver education and training required pursuant to rule 657—13.32(155A).

d. Ensuring that a qualified pharmacist is available and accessible at all times to respond to the questions and needs of other health professionals, the patient, or the patient's caregiver.

e. Identifying activities and processes that are deemed high-risk, high-volume, or problem-prone and providing effective corrective actions to remedy these activities and processes.

[**ARC 0596C**, IAB 2/6/13, effective 3/13/13]