657—20.10(124,126,155A) Drug compounding controls. Accountability for quality control is the responsibility of the compounding pharmacist.

20.10(1) *Procedures required.* Procedures for the compounding of drug products shall be written, implemented, and followed to ensure the safety, identity, strength, quality, and purity of the finished product. Such procedures shall include a listing of the bulk drug substances and components, their amounts in weight or volume, the order of bulk drug substance and component addition, and a description of the compounding processes. All equipment, utensils, and the container closure system relevant to the sterility and stability of the intended use of the compounded drug product shall be listed as necessary.

20.10(2) *Accuracy.* Components and bulk drug substances used in the compounding of drug products shall be accurately weighed, measured, or subdivided as appropriate. These operations shall be verified at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component or bulk drug substance is removed from the original container and stored in another container, the new container shall be identified with the name and lot number of the component or bulk drug substance.

20.10(3) *Record.* A production record shall be prepared and kept for each drug product compounded for an individual patient. The record shall include the following information:

a. Production date;

b. List of ingredients and quantity of each ingredient used;

c. Initials of each person involved in each of the compounding steps;

d. Initials of each pharmacist verifying each of the compounding steps;

e. Internal control or prescription number and, if the prescription is filled using a product compounded in bulk pursuant to rule 20.11(126), the internal control number assigned to the batch and recorded in the batch production record.

20.10(4) *Product testing and examination.* To ensure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established, implemented, and followed that describe the tests or examinations to be conducted on the product being compounded to monitor the output and to validate the performance of compounding processes that may be responsible for causing variability in the final drug product. Control procedures shall include, but are not limited to, the following as appropriate:

a. Capsule weight variation;

b. Adequacy of mixing to ensure uniformity and homogeneity;

c. Clarity, completeness, or pH of solutions.

20.10(5) *Sterilization.* Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purported to be sterile, including validation of any sterilization process, shall be established and followed.

20.10(6) *Label information required.* The label affixed to or on the dispensing container of any compounded drug product dispensed by a pharmacy pursuant to a prescription drug order, excluding a sterile product compounded pursuant to 657—Chapter 13, shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed and compounded for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the compounded drug product is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. The name and quantity or percentage of each bulk drug substance (active ingredient) contained in the compounded drug product. The use of auxiliary labels to accommodate this information is acceptable;

h. The initials or other unique identification of the dispensing pharmacist.

20.10(7) *Labeling—expiration date.* When applicable, the compounded product shall be labeled with an expiration date based on published data. When such data is unavailable, expiration dating shall be based on professional judgment or appropriate testing.

20.10(8) *Labeling and control of excess products.* When a quantity of a compounded drug product is prepared in excess of that to be initially dispensed, the excess product shall be labeled, stored, and accounted for pursuant to rule 20.11(126).