657—13.11(155A) Low-risk preparations.

13.11(1) *Conditions defined.* Preparations compounded under all of the following conditions are at a low risk of contamination.

a. The preparations are compounded with aseptic manipulations entirely within ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices.

b. The compounding involves only transferring, measuring, and mixing no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the preparation.

c. Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, containers of other sterile products, and containers for storage and dispensing.

d. In the absence of the preparation's passing a sterility test and provided that the preparation is properly stored before administration, storage periods shall not exceed the following:

(1) At controlled room temperature for 48 hours;

(2) At a cold temperature for 14 days; or

(3) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days.

13.11(2) *Examples.* Examples of low-risk compounding include:

a. The single-volume transfer of sterile dosage forms from ampoules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. When ampoules are employed, solution content shall be passed through a sterile filter to remove any particles.

b. The manual measuring and mixing of no more than three manufactured products including an infusion or diluent solution to compound drug admixtures and nutritional solutions.