657—13.11 (155A) Low-risk preparations and low-risk preparations with 12-hour or less beyond-use date.

13.11(1) *Conditions defined—low-risk preparations.* 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 not more than three commercially manufactured packages of sterile products and not more than two entries into any one container (e.g., bag, vial) of sterile product or administration container or device 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 between minus 25 and minus 10 degrees Celsius for 45 days.

13.11(2) *Examples—low-risk preparations.* 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.

13.11(3) *Low-risk preparations with 12-hour or less beyond-use date.* If the primary engineering control device is a CAI and does not meet the requirements described in subrule 13.27(3) or is a BSC or LAFW that cannot be located within an ISO Class 7 buffer area, then only low-risk nonhazardous and radiopharmaceutical preparations compounded pursuant to a prescriber's order for a specific patient may be prepared, and administration of such preparations shall commence within 12 hours of the start of compounding or as recommended in the manufacturers' package insert, whichever is less. Preparations shall meet all four of the following criteria:

a. The primary engineering control device shall be certified and shall maintain ISO Class 5 for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of preparation contamination.

b. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, food preparation areas, or other areas presenting a risk of contamination.

c. Personnel shall be appropriately garbed and shall perform appropriate cleansing activities prior to compounding. Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.

d. Appropriate procedures for cleaning and disinfecting the sterile compounding areas, for personnel training and competency evaluation, for aseptic practices and cleaning or disinfecting processes, and for environmental air sampling and testing shall be followed.