657—13.12(155A) Medium-risk preparations.

13.12(1) *Conditions defined.* Preparations compounded aseptically under low-risk conditions with one or more of the following additional conditions are at a medium risk of contamination.

a. Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile preparation for administration either to multiple patients or to one patient on multiple occasions.

b. The compounding process includes complex aseptic manipulations other than the single-volume transfer.

c. The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

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 30 hours;

(2) At a cold temperature for 9 days; or

(3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days.

13.12(2) *Examples.* Examples of medium-risk compounding include:

a. Compounding total parenteral nutrition fluids, using manual or automated devices and involving multiple injections, detachments, or attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

b. Filling reservoirs of injection or infusion devices with more than three sterile drug products and evacuating air from those reservoirs before dispensing the filled device.

c. Transferring volumes from multiple ampoules or vials into one or more final sterile containers.