657—13.13(155A) High-risk preparations.

13.13(1) *Conditions defined.* Preparations that are either contaminated or likely to become contaminated with infectious microorganisms when compounded under any of the following conditions are at a high risk of contamination.

a. Nonsterile ingredients, including manufactured products not intended for sterile use, are incorporated or a nonsterile device is used in the compounding process before terminal sterilization.

b. Sterile contents of commercially manufactured products, preparations that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers intended for the preparation, transfer, sterilization, and packaging of preparations are exposed to air quality inferior to ISO Class 5 for more than one hour.

c. Nonsterile procedures such as weighing and mixing in air quality inferior to ISO Class 7 are performed before sterilization, compounding personnel are not properly garbed and gloved, or nonsterile water-containing preparations are stored for more than six hours.

d. The chemical purity and content strength of bulk ingredients, whether the ingredients are in opened or unopened packages, are not verified by examination of labeling and documentation of suppliers or by direct determination.

e. For a sterilized high-risk preparation, in the absence of the preparation's passing a sterility test, the storage periods shall not exceed the following:

(1) At controlled room temperature for 24 hours;

(2) At a cold temperature for 3 days; or

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

13.13(2) *Examples.* Examples of high-risk compounding include:

a. Dissolving nonsterile bulk drugs or nutrient powders to make solutions that will be terminally sterilized.

b. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.

c. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95 percent by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

d. Exposing the sterile ingredients and components used to prepare and package the preparation to air quality inferior to ISO Class 5 for more than one hour.