657—13.14(155A) Immediate-use preparations. The immediate-use provisions of this rule are intended only for those situations where there is a need for emergency or immediate administration of a sterile preparation. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the compounding of the preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Immediate-use preparations are not intended for storage for anticipated needs or for batch compounding. Medium-risk and high-risk preparations shall not be compounded as immediate-use preparations. Immediate-use preparations are exempt from the provisions of rule 13.11(155A) for low-risk preparations only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container or device. Hazardous drugs shall not be compounded as immediate-use preparations.

2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed one hour.

3. During compounding, aseptic technique is followed and, if the preparation is not immediately administered, the preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other sterile preparations, and direct contact with outside surfaces.

4. Administration begins not later than one hour after compounding of the preparation is completed.

5. If administration has not begun within one hour after compounding of the preparation is completed, the preparation is promptly and safely discarded.

6. Unless immediately and completely administered by the person who compounded the preparation or unless immediate and complete administration is witnessed by the person who compounded the preparation, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who compounded the preparation, and the exact one-hour beyond-use date and time.