

657—13.15(155A) Utilization of single-dose and multiple-dose containers. Pharmacies utilizing single-dose and multiple-dose containers in sterile compounding shall comply with the following:

1. Single-dose containers that are opened or needle-punctured shall be used within one hour if opened in air quality conditions inferior to ISO Class 5.
2. Single-dose vials that are continuously exposed to ISO Class 5 air shall be used within six hours after initial needle puncture.
3. Opened single-dose ampoules shall not be stored for any period of time under any air quality conditions.
4. Multiple-dose containers that are entered or opened shall be used within 28 days of initial entry or opening unless otherwise specified by the manufacturer.
5. Multiple-dose and single-dose sterile products shall not be combined for use as multiple-dose applications.