

These requirements are specific to the automated compounding *hardware* and its end product, not personnel, and are current as of the initial release of USP-NF Chapter <797>.

Classification

- Automated compounders prepare CSPs (compounded sterile preparations) from multiple sterile sources, therefore these multi-ingredient solutions fall into Medium-Risk Level.

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

Environmental Quality and Control

- Sterile product preparation must take place in an ISO Class 5 (former class 100) environment for air quality.
- Buffer or anteroom to the sterile preparation area must have ISO Class 8 air quality.

Equipment

- Equipment and devices used to compound CSPs must be consistently capable of proper operation within acceptable tolerance limits.
- Written procedures are required to outline calibration, annual and routine maintenance, monitoring for proper function and appropriate equipment use and specified time frames for the above activities.
- Results from calibration and maintenance activities must be documented and kept on file for the life of the equipment.

Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding

- See also the general information Chapter 1225 for verification parameters.
- Accuracy should be determined to ensure that the correct quantities of individual components are being delivered.
- Equipment precision should be determined by keeping a daily record of accuracy assessments and reviewing the results over time. This review should take place at least weekly.
- Finished CSPs are individually inspected in accordance with written procedures after compounding.
- Written procedures for double-checking compounding accuracy must be followed for every CSP during preparation and immediately prior to release. This system must meet state regulations and include label accuracy and the accuracy of the addition of ingredients used to prepare the CSP and their volumes/quantities. When practical, confirm measurement accuracy by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate density value or specific gravity of the measured fluid.
- Correct density or specific gravity values programmed into ACDs that measure by weight using the quotient of the programmed volume divided by the density or specific gravity must be confirmed to be accurate before and after delivering volumes of the liquids assigned to each channel or port (page 11).
- A formal Quality Assurance plan must be in place to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in the Chapter.