
SUBJECT/TITLE: CERTIFICATION PROCEDURES FOR ASEPTIC TECHNIQUE AND PREPARATION OF PARENTERAL DRUGS AND CLEAN ROOM ENVIRONMENTAL CONTROL PROCEDURES**POLICY:**

The University of Iowa Health Care Department of Pharmaceutical Care is a government licensed pharmacy for sterile dose product preparation that is compliant with USP <797> standards and complies with local/state/federal regulations.

- A. All staff preparing or supervising the preparation of sterile products will complete certification prior to compounding sterile products or supervising the compounding of sterile products. Staff who compound or supervise preparation of sterile products will complete recertification per internal policy.
- B. Staff complete core competencies of USP <797> standards which can include written competencies and demonstration of competency. Staff will be certified to prepare sterile compounds according to department policies.
- C. Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination, including critical sites. Certification of compounding areas occurs at least every 6 months per USP <797> standards and corrective actions are taken if not meeting standards. Certification results and monitoring of compounding areas will not be provided to study or sponsor personnel.
- D. The University of Iowa Health Care Department of Pharmaceutical Care is inspected and licensed by the Iowa Board of Pharmacy and accredited by the Joint Commission, both of which review our compliance with existing aseptic technique and clean room control procedures.
- E. A copy of the government (Iowa) pharmacy license can be provided upon request.
- F. Internal policies will not be shared with study or sponsor personnel. No internal training documentation will be provided to study or sponsor personnel.

DEFINITIONS: None

Approval History

Date created: 8/25

Approved by the Director and Select Pharmacy Administrative Staff: 8/25

Revised:

Reviewed: