

Exhibit 3-41 F
Assessment of Aseptic Technique
Responsible Personnel: Designated Person

The responsible person will mark an X after each space for which the person being assessed has acceptably completed the described activity. Mark NA if the activity is not applicable to the assessment or NO if the activity was not observed.

- ___ Performs proper hand hygiene, garbing, and gloving procedures according to the local standard operating procedures
- ___ Disinfects the International Organization of Standards (ISO) Class 5 device surfaces with an appropriate agent
- ___ Disinfect components/vials with the appropriate agent
- ___ Introduces only essential materials
- ___ Does not interrupt, impede, or divert flow of first air to critical sites
- ___ Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in the ISO Class 5 work area
- ___ Performs manipulations only in the appropriate direct compounding area (DCA) of the ISO Class 5 area
- ___ Does not expose the critical sites to contact contamination or worse than ISO Class 5 air
- ___ Disinfect stoppers, injection ports, and ampule necks by wiping with sterile 70% isopropyl alcohol (IPA) and allows sufficient time to dry
- ___ Affixes needles to syringes without contact contamination
- ___ Punctures vial stoppers and spikes infusion ports without contact contamination
- ___ Labels preparations correctly
- ___ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged manipulation
- ___ Cleans, set up and calibrates automated compounding devices (i.e., "TPN compounder") according to the manufacturer's instructions
- ___ Disposes of sharps and waste according to local policy or recognized guidelines

Signature of Personnel Assessed

Printed Name

Date

Signature of Evaluator

Printed Name

Date