

**Disinfection and sterilization.**

Instruments and other reusable equipment used by licensees who perform or participate in invasive procedures shall be appropriately disinfected and sterilized according to acceptable and prevailing standards for disinfection and sterilization which shall include at least the following:

- (A) Instruments and devices that enter the patient's vascular system or other normally sterile areas of the body shall be sterilized before being used for each patient; ~~and~~
- (B) Instruments and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces shall be sterilized when possible, or undergo high-level disinfection if they cannot be sterilized before using for each patient; ~~and~~
- (C) ~~Heat sterilization must be utilized for all instruments~~ Instruments and devices that are able to withstand repeated exposure to heat shall be heat sterilized. Sterilization shall must be accomplished by autoclave, dry heat, unsaturated chemical vapor, ethylene oxide, or any other FDA/EPA-approved method; ~~and~~
- (D) ~~A high level disinfection process must be used for those instruments~~ Instruments and items that cannot withstand heat sterilization shall be subjected to a high level disinfection process; ~~and~~
- (E) Heat sterilizing devices shall must be tested for proper function on a weekly basis by means of a biological monitoring system that indicates microorganism kill. Documentation shall must be maintained either in the form of a log reflecting dates and person(s) conducting the testing or copies of reports from an independent testing entity. The documentation shall be maintained for a period of at least two years. In the event of a positive biological spore test, the licensee must take immediate remedial action to ensure that heat sterilization is being accomplished; ~~and~~
- (F) Surface disinfection:
  - (1) Environmental surfaces that are contaminated by blood or other body fluids shall must be disinfected with a chemical germicide that is registered with the environmental protection agency as a "hospital disinfectant" or sodium hypochlorite and is mycobactericidal at use-dilution. The disinfection process shall must be followed before ~~between~~ each patient.
  - (2) Impervious backed paper, aluminium foil or plastic wrap shall must be used to cover surfaces that may be contaminated by blood or other body fluids and that are difficult or impossible to disinfect. The cover shall must be removed, discarded and then replaced between patients; and

- (G) Single use items used in treating a patient, which have become contaminated by blood or other body fluids, ~~shall~~ ~~must~~ be discarded and not reused, unless sterilized and reused in accordance with current guidelines established by the FDA. Single use items being reused in treating a patient ~~shall~~ ~~must~~ be adequately cleaned and sterilized; ~~Single use items shall not be reused if~~ the items' physical characteristics and quality ~~must not~~ have been adversely affected; ~~or if~~ ~~and~~ the items ~~must remain~~ ~~capable~~ are incapable of being reused safely and effectively for their intended use.

Effective: 02/28/2004

R.C. 119.032 review dates: 11/17/2003 and 12/31/2007

---

Certification

---

Date

Promulgated Under: 119.03  
Statutory Authority: 4731.05  
Rule Amplifies: 4731.051, 4731.22  
Prior Effective Dates: 10/1/94, 12/31/97