# Ohio Administrative Code

## Rule 4731-17-04 Disinfection and sterilization.

Effective: May 31, 2021

Instruments and other equipment classified by the FDA as reusable, 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;

(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;

(C) Instruments and devices that are able to withstand repeated exposure to heat shall be heat sterilized. Sterilization shall be accomplished by autoclave, dry heat, unsaturated chemical vapor, ethylene oxide, hydrogen peroxide gas plasma, or any other FDA/EPA-approved method;

(D) Instruments and items that cannot withstand heat sterilization shall be subjected to a high level disinfection process, including compliance with any manufacturer's instructions for disinfection;

(E) Heat sterilizing devices shall be tested for proper function on a weekly basis by means of a biological monitoring system that indicates microorganism kill. Documentation shall 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;

(F) Surface disinfection:

(1) Environmental surfaces that are contaminated by blood or other body fluids shall 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 be followed before each patient; and

(2) Impervious backed paper, aluminum foil or plastic wrap shall 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 be removed, discarded and then replaced between patients.

(G) Single use items used in treating a patient, which have become contaminated by blood or other body fluids, shall 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 be adequately cleaned and sterilized. Single use items shall not be reused if the items' physical characteristics and quality have been adversely affected or if the items are incapable of being reused safely and effectively for their intended use.