**Section 518.1950 Sterilization and Processing of Supplies**

a) All sterilization and processing of all sterile supplies and equipment shall be under competent, qualified supervision.

1) The director or person responsible for sterile supplies and equipment shall be responsible to the chief executive officer. This person shall be qualified for the position by education, training and experience.

2) The number of supervisory and support personnel shall be related to the scope of the services provided. New employees shall receive initial orientation and on-the-job training, and all employees shall participate in a continuing in-service education program, which shall be documented.

3) Educational efforts, though directed primarily at sterile-supply processing and handling techniques, shall also include management concepts, safety, personal hygiene, health requirements and hand-washing, and work attire.

b) Written policies and procedures shall be established for the decontamination and sterilization activities performed in the freestanding emergency center and shall relate, but are not limited, to the following:

1) Receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing reusable items.

2) Assembly, wrapping, storage, distribution, and quality control of sterile equipment and medical supplies. Load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

3) Use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.

4) Designation of the shelf life for each FEC-wrapped and -sterilized medical item and, to the maximum degree possible, for each commercially prepared item.

A) Designation of a shelf life may be a specific expiration date, i.e., 30 days, six months, etc., based on manufacturer's recommendation, a nationally recognized authority, or other standard approved by the owning or controlling hospital's Infection Control Committee.

B) Designation of shelf life may be event related if policies and procedures, approved by the owning or controlling hospital's Infection Control Committee, address at least the following:

i) Requirements for wrapping, storing and rotating sterile supplies;

ii) Definition of an event that may cause a sterile item to be or be suspected of being compromised, such as the package being wet or torn, or the seal being broken or tampered with;

iii) Clear direction that final inspection of the package and the ultimate decision to use the contents of the package rest with the clinician; and

iv) Orientation, in-service and other follow-up to assure that all necessary staff understand and implement the policies and procedures.

C) A facility may choose to use both a specific expiration date and event-related shelf life designation specific for certain wrappings, areas of the FEC, etc., as long as the policies and procedures, as approved by the Infection Control Committee, and training of staff define this practice.

5) Acquisition of supplies after normal working hours or any time the central supply service or sterile supply unit is considered "closed" or unstaffed.

6) Preventive maintenance of all central supply service equipment, including performance verification records and reports.

7) The recall and disposal or reprocessing of outdated sterile supplies.

8) The emergency collection and disposition of supplies when special warnings have been issued by the manufacturer. The attending physician shall be notified if patient exposure is known.

9) Specific aeration requirements for each category of gas-sterilized items to eliminate the hazard of toxic residues.

10) The cleaning and sanitizing of work surfaces, floors, utensils and equipment used in central supply service functions.

c) Space shall be provided for the efficient operation of all central supply service functions. Functional design and work-flow patterns shall separate soiled and contaminated supplies from supplies that are clean and sterile. Equipment of adequate design, size and type shall be provided for decontaminating, disinfecting, cleaning, packaging, sterilizing, storing and distributing medical instruments, supplies and equipment used in patient care.

d) Equipment and Procedures

1) The facilities, equipment, and procedures for cleanup, preparation, and sterilization shall be adequate to allow proper cleaning, processing, and sterilizing of patient care supplies and equipment.

2) When cleanup, preparation, and sterilization functions are carried out in the same room or unit (as in a central sterilizing department), the physical facilities and equipment and the policies and procedures for their use shall separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment.

3) Sterilization equipment shall be maintained in good repair and be under a preventive maintenance program.

4) All pressure steam autoclaves shall have recording thermometers, and the sterilization performance shall be otherwise monitored.

e) Sterilization of Instruments and Utensils

1) All surgical instruments not adversely affected by high temperature shall be sterilized by pressure steam sterilization.

2) Whenever possible, throughout the FEC, sterilization shall be accomplished by pressure steam sterilization. Hot air sterilization or gas sterilization may be used. When gas sterilization is used, there shall be policies and tested procedures for proper aeration to permit safe use. Pressure steam sterilization of reusable syringes and needles is required.

3) All instruments, whether used on infected cases or clean cases, shall be cleaned before sterilization. Instruments used on infected cases shall be disinfected before transport to central supply.

4) Boiling is not an approved method of sterilization.

f) Water Sterilization

1) When non-commercial sterile water is used, water sterilization equipment shall be maintained and operated in a manner that will protect the sterilized water from contamination.

2) An acceptable method for checking the sterility of the water shall be used. Water may be sterilized either in water sterilizers or autoclaved in appropriate flasks.

g) Sterilization and Storage of Supplies and Equipment

1) Supplies and equipment shall be properly wrapped and labeled before sterilization.

2) The effectiveness of sterilization shall be checked. This shall include bacteriological testing of all sterilization units throughout the facility. Indicators shall be used to show that a wrapped package has been sterilized. A procedure shall be established for the recall of expired or inadequately sterilized goods for both in-house and commercially sterilized supplies and equipment.

3) Supplies and equipment commercially prepared so as to retain sterility indefinitely are acceptable. The FEC shall verify the sterility of these materials.

4) Sterile equipment and supplies shall be stored properly in clean cabinets, cupboards or other suitable enclosed spaces. An orderly system of rotation of supplies is recommended so that supplies stored first will be used first.

(Source: Amended at 33 Ill. Reg. 8317, effective June 4, 2009)