**Section 250.1090 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 central services shall be responsible to the chief executive officer either directly or through a designated department head. The director of the central sterile supply shall be qualified for the position by education, training, and experience and shall be a member of the Infection Control Committee. (See Section 250.1100(a).)

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 work attire.

b) There shall be written policies and procedures for the decontamination and sterilization activities performed in central services and elsewhere in the hospital. The hospital shall comply with the Centers for Disease Control and Prevention Guidelines for Disinfection and Sterilization in Healthcare Facilities. These policies and procedures shall include, but are not limited to, the following:

1) The receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing of reusable items.

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

3) The 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 hospital-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 facility's Infection Control Committee.

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

i) requirements for wrapping, storage and rotation of 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 the 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 training 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 hospital, etc., as long as the policies and procedures, as approved by the Infection Control Committee, and the training of staff define this practice.

5) Acquisition of supplies after normal working hours or any time the central 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 expired or inadequately sterilized supplies.

8) The emergency collection and disposition of supplies when special warnings have been issued by the manufacturer. The attending physician shall be notified when 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 service functions.

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

d) Equipment and procedures

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

2) When clean-up, 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 be such as to effectively 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 under the provisions of a preventive maintenance program of the Engineering and Maintenance Services. (Refer to Subpart P.)

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

e) Sterilization of instruments and utensils

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

2) The steam method of sterilization is the preferred method for sterilizing medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture. Low-temperature sterilization technologies (e.g., Ethylene Oxide (EtO), hydrogen peroxide gas plasma) may be used for reprocessing patient care equipment that is heat or moisture sensitive. In addition, a peracetic acid immersion system of sterilization may be used to sterilize heat-sensitive immersible medical and surgical items, and dry-heat sterilization may be used to sterilize items (e.g., powders, oils) that can sustain high temperatures. Operating parameters and guidelines for each method or system of sterilization shall be followed for whichever method is used.

3) All instruments shall be thoroughly cleaned before sterilization.

4) Boiling is not an approved method of sterilization.

f) Water sterilization

1) When non-commercial sterile water is utilized, 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 utilized. Water may be sterilized either in approved water sterilizers or autoclaved in approved 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 hospital sterilization shall be checked. Mechanical, chemical, and biologic monitors shall be used to ensure the effectiveness of the sterilization process. Indicators shall be used to show that the items have 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. Refer to Section 250.1100(a).

3) Supplies and equipment commercially prepared so as to retain sterility indefinitely are acceptable. The hospital shall satisfy itself of the sterility of such 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.

h) Transmissible spongiform encephalopathies (TSEs)

1) Records shall be maintained for at least 20 years regarding quarantine, disposal, decontamination, and sterilization of surgical instruments used for patients with a confirmed or suspected TSE.

2) For the purposes of this Section, TSEs are a group of rapidly progressive, invariably fatal neurodegenerative diseases that affect both humans and animals. TSEs in humans include Creutzfeldt-Jakob disease (CJD), kuru, Gerstmann-Straussler-Scheinker syndrome (GSS), fatal familial insomnia (FFI), and variant CJD (vCJD).

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