**CENTRAL SERVICE REGULATIONS FOR HOSPITALS**

_Last updated July 2014_

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<th>STATE</th>
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| Alabama| ALABAMA STATE BOARD OF HEALTH ALABAMA DEPARTMENT OF PUBLIC HEALTH DIVISION OF LICENSURE AND CERTIFICATION CHAPTER 420-5-7: HOSPITALS Ala. Admin. Code r. 420-5-7, Appendix B | (1) Disposable equipment is recommended for administering care to patients in isolation.  
(2) The central sterilizing and supply room should be located adjacent to the surgical department.                                                                                                               |
7 AAC 12.730. Central service

(a) If a facility processes sterilized instruments and supplies, it must meet the requirements in this section. If a facility receives sterilized instruments and supplies from another entity through contract or agreement, the facility must ensure the contractor meets the requirements in this section.

(b) A facility must maintain a separate area for processing, decontamination, if necessary, and storage of sterile supplies and materials.

(c) A facility must develop and implement written policies and procedures for the cleaning, antimicrobial processing, and storage of supplies and equipment to prevent the transmission of infection through their use.

(d) Traffic in an area designated for processing, decontamination, and storage of supplies must be restricted to properly attired authorized personnel. Birth centers, frontier extended stay clinics, and nursing homes are not required to comply with this subsection.

(e) Shipping cartons may not be stored with sterile products.

(f) A facility must retain records of bacteriological efficiency monitoring of autoclaves at recommended frequency for three years.

(g) Instructions for the operation of autoclaves must be posted near the equipment.

(h) Each facility must maintain a retrieval system for supplies whose sterility is questionable.

(i) A hospice agency that does not provide inpatient care on agency premises is exempt from the requirements of this section.
Arkansas

007 DEPARTMENT OF HEALTH
05 HEALTH FACILITY SERVICES
002. CRITICAL ACCESS HOSPITALS

Section 34 Specialized Services: Central Sterilization and Supply.

A. Each hospital shall provide central medical and surgical supply services with facilities that are responsible for processing, sterilizing, storing, distributing supplies and equipment to all units of the hospital. (Refer to Section 62, Physical Facilities, Central Medical and Surgical Supply Department, for space and equipment requirements.)

B. The central sterilization and supply service shall be under the direct supervision of a Registered Nurse or other qualified person who is trained in management, aseptic procedures, supply processing, and control methods which are applicable to central sterilization and supply service.

C. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department and/or person(s) conducting the review.

D. Policies and procedures shall include:

1. Job descriptions
2. Infection control measures;
3. Assembly and operation of equipment;
4. Safety practices;
5. Orientation for new employees;
6. Care and cleaning of equipment;
8. Receiving, decontaminating, cleaning, preparing, disinfecting, and sterilizing reusable items;
9. Assembling and wrapping of packs (to include the double-wrapped techniques);
10. Storage and distribution of sterile equipment/medical supplies;
11. Use of chemical indicators and biological spore tests for sterilizers;
12. Recalling and disposing/reprocessing of outdated sterile supplies;
13. Cleaning and disinfecting of surfaces, utensils, and equipment;
14. Specifications for cold-liquid sterilization and gas sterilization (if used); and 15. Collection and disposal of supplies recalled by the manufacturer.

E. There shall be an ongoing QA/PI program specific to the area.

F. Precautions shall be exercised to prevent the mixing of sterile and unsterile supplies and equipment. The precautions shall be set forth in written policies.

G. Procedures shall be developed for unloading and transporting flash sterilized items. The procedures shall be developed with the assistance of the Infection Control Committee and shall provide for the aseptic transfer within the physical constraints of the facility.

H. Relevant educational programs shall be conducted at regularly scheduled intervals with no less than 12 per year. There shall be written documentation with employee signature, program title/subject, presenter, date and outline or narrative of presented program.

I. A liaison with the Infection Control Committee shall be maintained.

J. Records shall be maintained of all autoclave loads, both routine and "flash," which shall include the date, time, lot number (on routine loads), the time at temperature (where a recorder is not available), item(s) sterilized and shall identify the person performing the task.

K. Autoclaves shall meet the following requirements:
1. The efficacy of autoclaves, both for routine and "flash" use, shall be determined weekly through the use of biological spore monitors;  
2. The results of all biological spore monitoring shall be reported to the Infection Control Committee; and  
3. Failures of the biological spore test shall be brought to the attention of the Infection Control Officer or designee immediately so the appropriate surveillance measures can be initiated;  

NOTE: All materials sterilized from the date of the biological spore monitor failure to the last successful biological spore monitor shall be resterilized before use.  
L. All autoclaves within the facility shall be maintained in accordance with the manufacturer's written directions. Records shall be maintained of all maintenance and repairs for the life of the equipment.  

M. Chemical indicators for sterility shall be used with each cycle.  
N. The facility shall validate compliance and efficacy of the sterilization policy through the quality review process. The sterilization policy shall describe the mechanism used to determine the shelf life of sterilized packages. The policy shall:  

1. Be consistent with published industry standards (AAMI and APIC).  
2. Stress that sterility is related to integrity of pack regardless of whether expiration dating or event-related expiration is utilized.  
O. Event-related/Indefinite dating of sterile packs is acceptable.  

NOTE:  
1. Stock rotation shall be based on the "first in-first out" principle.  
2. Sterile storage areas shall maintain a temperature (75°F) and a relative humidity of 70%. Ventilation shall be 10 air changes per hour and shall follow clean to dirty flow.  
3. The interior of the dust cover shall not be considered sterile.
4. Indefinitely dated items shall be labeled with the date of sterilization and state "contents sterile unless package is damaged." Packages that are wet, dropped on the floor, compressed, or torn shall be rejected.

5. The lot number or control number and expiration statement shall be visible through the package or another tag shall be placed on the outside.

6. Containers for sterilization systems shall be scientifically proven suitable for the specific sterilization cycle used; the container system shall be verified as the correct one for the cycle. (Manufacturer's instructions shall be followed.)

7. Double-wrapped shall mean the end results of the wrapping technique will yield an envelope within an envelope.

8. The date of sterilization and load control number shall be placed on each sterilized pack.

P. Flash (autoclaving) shall be restricted to unplanned or emergency situations. Flash sterilization shall never be used as a convenience to compensate for inadequate inventories of instruments or implantables. Flash sterilization of implantables shall be restricted to the direst circumstances.

Q. Items which are to be flash sterilized shall be cleaned and decontaminated before the sterilization process.

R. Traffic areas in which flash sterilization is carried out shall be restricted to authorized personnel wearing surgical attire consisting of surgical scrubs, shoe covers, masks, and hair covers. The sterilizer shall not be located adjacent to any potential sources of contamination such as scrub sinks, clinical sinks or hoppers, wash sinks, linen or trash disposal areas.

S. For flash sterilization, minimal time at effective temperature shall conform to the following:

T. Items that previously have been packaged, sterilized, and issued, but not used may be
returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; such items may be dispensed when needed.

Items that previously have been packaged, sterilized and issued to the patient care units or other areas where the environment is not controlled shall be discarded if they are single use items, or unwrapped, and reprocessed through decontamination if they are reusable.

U. Sterile materials must be stored 8 to 10 inches from the floor and at least 18 inches from the ceiling and at least two inches from outside walls. Items shall be positioned so that packages are not crushed, bent, compressed, or punctured and sterility is not compromised.

V. All sterilization techniques other than steam (plasma, ethylene oxide, chemical, etc.) shall follow the manufacturer's directions and meet all state and federal regulations.

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<th>California</th>
<th>TITLE 22. SOCIAL SECURITY DIVISION 5. LICENSING AND CERTIFICATION OF HEALTH FACILITIES, HOME HEALTH AGENCIES, CLINICS, AND REFERRAL AGENCIES CHAPTER 1. GENERAL ACUTE CARE HOSPITALS ARTICLE 8. PHYSICAL PLANT</th>
<th>§ 70831. Central Sterile Supply</th>
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<td>(a) Each hospital shall provide, prepare, sterilize and store sufficient sterile supplies and medical and surgical equipment and shall dispense them to all services in the hospital. The operation of this service shall be carried out in an area designated, equipped and staffed for this purpose.</td>
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<td>(b) A person shall be designated to be in charge of the central sterile supply.</td>
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<td>(c) There shall be written procedures developed and maintained pertaining to the cleaning, preparation, disinfection and sterilization of utensils, instruments, solutions, dressings and other articles.</td>
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<td>(d) There shall be effective separation of soiled or contaminated supplies and equipment</td>
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from the clean and sterilized supplies and equipment.

(e) Sterile supplies and equipment shall be stored in clean cabinets, cupboards or other satisfactory spaces. An orderly system of rotation of supplies shall be used so that supplies stored first will be used first.

§ 72619. Space and Equipment for Autoclaving, Sterilizing and Disinfecting

(a) A facility shall:

(1) Maintain disposable sterile supplies in the amount necessary to meet the anticipated needs of the patients, or
(2) Maintain autoclave equipment, or
(3) Make contractual arrangements for outside autoclaving and sterilizing services.

(b) If a facility maintains a central supply and sterilizing area, it shall include but not be limited to:

(1) An autoclave or sterilizer, which shall be maintained in operating condition at all times.
   (A) Autoclaves shall be equipped with time recording thermometers in addition to the standard mercury thermometers, except for portable sterilizers and autoclaves.
   (B) Instructions for operating autoclaves and sterilizers shall be posted in the area where the autoclaves and sterilizers are located.
(2) Work space.
(3) Storage space for sterile supplies.
(4) Storage space for unsterile supplies.
(5) Equipment for cleaning and sterilizing of utensils and supplies.
(c) The facility shall provide for:

1. Effective separation of soiled and contaminated supplies and equipment from the clean and sterilized supplies and equipment.
2. Clean cabinets for the storage of sterile supplies and equipment.
3. An orderly system of rotation of supplies so that the supplies stored first shall be used first and that multi-use supplies shall be reautoclaved as they become outdated.
5. Loading of the autoclave or sterilizer.
6. Checking of recording and indicating thermometers. Recording thermometer charts shall be on file for one year.
7. Conducting monthly bacteriological tests. Reports of test results for the last 12 months shall be retained on file.
8. Length of aeration time for materials that are gas-sterilized.
(1) Processing, sterilizing, and storing. A combination of controls or indicators shall be used to determine the effectiveness of the sterilization process. Bacteriological methods shall be used to evaluate the effectiveness of sterilization, by at least monthly cultures with records maintained.

(2) Written policies and procedures shall be established for all functions of central medical-surgical supply services. Such written procedures shall include, but not be limited to, obtaining, cleaning, processing, sterilizing, storing and issuing supplies. These policies and procedures shall be periodically reviewed by the Infection Control Committee, as applicable.

(3) Policies shall be established to provide supervision and training programs for all personnel involved in central medical-surgical supply operations and services.

(4) Water used for sterile solutions shall be distilled and sterilized in flasks which are resistant to heat, chemical, and electrical action.

(5) Dry heat and special chemical methods are available and acceptable for sterilization of materials which would be damaged by pressurized steam.

| Connecticut | NONE |
| Delaware | AGENCY 7. DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL SUB-AGENCY 1000. DIVISION OF AIR AND WASTE MANAGEMENT; AIR QUALITY MANAGEMENT SECTION |
| Section 9.0 Emission Standards for Hospital Ethylene Oxide Sterilizers. 9.2 Definitions. |
| "Hospital central services staff" means a healthcare professional, including manager and technician, who is either directly involved in or responsible for sterile processing at a hospital. |
| "Medically necessary circumstances" means circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally |
accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

"Sterilization facility" means the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing.

"Sterilization process" means any time when ethylene oxide is removed from the sterilization unit or combination sterilization unit through the sterilization unit vent.

"Sterilization unit" means any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing. As used in 9.0 of this regulation, the term includes combination sterilization units.

9.4 Standards.

9.4.1 The owner or operator of an affected source subject to 9.0 of this regulation shall comply with either 9.4.1.1 or 9.4.1.2 of this regulation, whichever is applicable.

9.4.1.1 The owner or operator of an aeration unit or sterilization unit that is not equipped with an air pollution control device shall only sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in 9.2 of this regulation.

9.6.1 The owner or operator of an affected source subject to 9.4.1.1 of this regulation shall demonstrate ongoing compliance with the requirements of 9.4.1.1 of this regulation by recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.
| DC       | TITLE 22. PUBLIC HEALTH AND MEDICINE  
| SUBTITLE B. HEALTH  
| CHAPTER 20. HOSPITALS  
| 22-B2033. CARE AND TREATMENT AREAS. | (b) Equipment and Supplies: The hospital shall have services and space to distribute, maintain, clean and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the hospital.  

(1) Durable Medical: The hospital shall ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.  

(2) Sterile Processing: The hospital shall have areas for decontamination and sterilizing of durable medical instruments and equipment.  

(A) The hospital shall provide separate central sterile processing and waste processing areas.  

(B) In new construction and where provided, central processing areas shall have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The hospital shall have hand-washing sinks in both clean and soiled rooms. |

| Florida | none |

| Georgia | TITLE 111: DEPARTMENT OF COMMUNITY HEALTH  
| CHAPTER 111-8 HEALTHCARE FACILITY REGULATION  
| CHAPTER 111-8-40 RULES AND REGULATIONS FOR HOSPITALS | 111-8-40-.17 Sterile Processing Services.  

Each hospital shall designate a sterile processing service area designated for the decontamination, cleaning, sterilizing of reusable equipment, instruments, and supplies.  

(a) With the collaboration of the infection control program, the staff providing sterile processing services shall develop and implement standardized policies and procedures that conform to generally accepted standards of practice for:  

1. Decontamination and cleaning of instruments and other items and description of reprocessing protocols for contaminated patient equipment;  

2. Disinfecting and/or sterilizing equipment and other items;  

3. Monitoring of the systems used for sterilization;
4. Procedures for ensuring the sterility of packaged instruments and supplies;
5. Recall of items; and
6. Mechanisms for protection of workers from exposure to blood and other potentially infectious materials and environmental hazards.

(b) The sterile processing service shall be staffed by qualified personnel.

### Hawaii

**TITLE 11. DEPARTMENT OF HEALTH**
**CHAPTER 93. HOSPITALS**

11-93. HOSPITALS

§ 11-93-35 Surgical department.

(f) There shall be adequate scrub-up facilities and work areas for the preparation, sterilization, and storage of instruments and supplies.

### Idaho

**IDAPA 16: DEPARTMENT OF HEALTH AND WELFARE**
**TITLE 03: DIVISION OF WELFARE**
**CHAPTER 14: RULES AND MINIMUM STANDARDS FOR HOSPITALS IN IDAHO**

IDAPA 16.03.14.410 (2013)

410. CENTRAL SERVICE.

The hospital shall provide an area for the cleaning, disinfection, packaging, sterilization, storing and distribution of medical/surgical patient care supplies.

01. Service Areas. The service shall be separated into the following areas:
   a. Receiving and cleaning of contaminated supplies; and
   b. Assembly area (packaging); and
   c. Sterilization area; and
   d. Sterile and nonsterile storage area.

02. Equipment and Supplies. Autoclaves, sterilizers, and other equipment shall be available to meet the needs of the hospital. Effective Date (10-14-88)

03. Policies and Procedures. Policies and procedures established for processing and reprocessing of all instruments and supplies shall be approved by the infection control committee and must include the following:
   a. Method of cleaning all equipment; and
   b. A listing of contents of package and material to be used for all items autoclaved or
Sterilization and Processing of Supplies

| Illinois | TITLE 77. PUBLIC HEALTH
| STATE OF ILLINOIS |
| SUBCHAPTER b. HOSPITALS AND LONG-TERM CARE FACILITIES |
| § 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, experience, and training in infection control.

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

c) Procedure for operation of autoclaves and sterilizers; and

d) Policy regarding shelf life of all types of packages; and

e) Policy regarding expiration dates of packages; and

f) Procedure for conducting daily check of thermometers, and recordings; and

g) Determination of temperature, time, pressures, and humidity for autoclaves and sterilizers; and

h) Procedure for recall and disposal or reprocessing; and

i) Policy regarding maximum size and weight of packs; and

j) Procedure for biological (spore) check of gas sterilizers, each load; and

k) Procedure for biological (spore) check of autoclave at least monthly; and

l) Policy establishing aeration periods for various kinds of materials that are gas sterilized; and

m) Procedure for cleaning and disinfection of all items that are not sterilized; and

n) Procedure for cleaning and sanitizing equipment and surfaces (housekeeping); and

o) Policy establishing that all water issued for respiratory therapy shall be sterile; and

p) Written infection control procedure; and

q) Procedure for the control of water used for respiratory therapy if that service is not responsible.

04. Inservice/Continuing Education. Documentation of all orientation and educational programs for each employee shall be present at the facility.

Illinois

| TITLE 77. PUBLIC HEALTH |
| DEPARTMENT OF PUBLIC HEALTH |
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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, experience, and training in infection control.
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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(a) Policies and procedures shall be established in writing for storage, maintenance, and distribution of supplies and equipment.

(b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled.

(c) Sterilizers and autoclaves shall be provided of appropriate type and necessary capacity to adequately sterilize instruments, utensils, dressings, water, operating and delivery room materials, as well as laboratory equipment and supplies. The sterilizers shall have approved control and safety features. The accuracy of instruments shall be checked periodically by an approved method. Adequate surveillance methods for checking sterilization procedures shall be employed.

(d) The date of sterilization or date of expiration shall be marked on all sterile supplies, and unused items shall be resterilized in accordance with written policies.
**Section 22. Central Medical and Surgical Supply Department.** The following areas shall be permanently separated from each other:

(1) Receiving and decontamination room. The room shall contain work space and equipment for cleaning medical and surgical equipment and for the disposal or processing of unclean material. Hand-washing facilities shall be provided.

(2) Clean workroom. This room shall be divided into work space, clean storage area, and sterilizing and sanitizing facilities. Hand-washing facilities shall be provided.

(3) Storage area for clean supplies and sterile supplies. The storage area may be in a designated area in the clean workroom.

(4) Equipment storage.

(5) Cart storage, if this type of system is utilized.

(6) Janitor's closet. The janitor's closet shall contain a floor receptor or service sink with storage space for housekeeping supplies and equipment to be utilized exclusively in this department.

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### Minnesota

**DEPARTMENT OF HEALTH**  
**CHAPTER 4640 HOSPITAL LICENSING AND OPERATION**  

**Subp. 4.** **STERILIZING FACILITIES.** Adequate work space, sterilizing space, and sterile storage space shall be provided. Sterilizers and autoclaves of the proper type and necessary capacity for the sterilization of utensils, instruments, dressings, water, and other solutions shall be provided and maintained in an operating condition. Special precautions shall be taken so that sterile supplies are readily identifiable as such and are completely separated from unsterile supplies. A central sterilizing and supply room is recommended. Provision of sterile water in flasks is recommended.

### Mississippi

**AGENCY 15. DEPARTMENT OF HEALTH**  
**SUB-AGENCY 016. PART 16: HEALTH FACILITIES; SUBPART 1: HEALTH FACILITIES LICENSURE AND CERTIFICATION**  
**CHAPTER 041. MINIMUM STANDARDS OF OPERATION FOR MISSISSIPPI HOSPITALS**  

**CMSR 15-016-041 (2014)**

**Subchapter 17 Central Sterile Supply.**

**Rule 41.17.1.** The following areas shall be separate:

1. **Receiving and Clean-Up Area.** To contain a two-compartment sink with two drain boards.

2. **Pack Make Up.** Shall have autoclaves, work counter and unsterile storage.

3. **Sterile Storage Area.** Should have pass-through to corridor.
| Missouri |
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| **TITLE 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES**  
**DIVISION 30 - DIVISION OF REGULATION AND LICENSURE**  
**CHAPTER 20 - HOSPITALS**  
**19 CSR 30-20.088 (2014)**  
**30-20.088 Central Services in Hospitals** |

30-20.088 Central Services in Hospitals

1. Central services shall be organized and integrated with patient care services in the hospital.

2. The director of central services shall be qualified by education, training and experience in aseptic technique, principles of sterilization and disinfection and distribution of medical/surgical supplies. The director shall be responsible to an administrative officer or a qualified designee.

3. Sufficient supervisory and support staff shall be assigned as related to the scope of services provided.

4. Sufficient space and equipment shall be provided for the safe and efficient operation of the services as determined by the scope of hospital services delivered.

5. Policies and procedures shall define the activities of all services provided. Sterilization and disinfection standards of practice shall be established. The principles of the Association for Practitioners in Infection Control, Association of Operating Room Nurses, Center for Disease Control and Prevention, American Society for Healthcare Central Service Personnel, Association for the Advancement of Medical Instrumentation, and others may be utilized to establish facility standards of practice for central services.

6. Written procedures shall specify how items stored in central services can be obtained when central services is considered closed.

7. Reprocessed packaged item(s) shall be identified as to content, show evidence of sterilization and be labeled indicating the sterilizer used and the load/cycle number. A policy on the shelf life of a packaged sterile item shall be established in accordance with acceptable standards of sterilization and dependent on the quality of the packaging.
material, storage conditions and the amount of handling of the item.

(8) Central services shall maintain documentation from the manufacturer that packaging material utilized for reprocessing is appropriate for this use. Expiration dates shall comply with the packaging material utilized.

(9) Sterile medical-surgical packaged items shall be handled only as necessary and stored in vermin-free areas where controlled ventilation, temperature and humidity are maintained. The integrity of sterile items shall be maintained throughout reprocessing, storage, distribution and transportation.

(10) Preventive maintenance of equipment shall be done as recommended by the manufacturer or as specified by hospital policy. Records shall be maintained as specified by hospital policy. Records shall include documentation that items processed by steam have undergone sufficient time, temperature and pressure and that items processed by ethylene oxide have undergone sufficient time, temperature, gas concentration and humidity to obtain pathogenic microbial kill.

(11) Ethylene oxide sterilized items shall be aerated as specified by hospital policy based on the manufacturer's recommendations to eliminate the hazards of toxic residue for both patient and staff.

(12) Principles of sterilization and disinfection as approved by the hospital's infection control committee shall apply throughout the hospital when central services activities are decentralized.
| Nebraska | TITLE 175. HEALTH CARE FACILITIES AND SERVICES LICENSURE (DEPARTMENT OF HEALTH AND HUMAN SERVICES) Nebraska Admin. Code Title 175, Ch. 9 (2014) | 9-007.02B2 Sterile Processing: The hospital must have areas for decontamination and sterilizing of durable medical instruments and equipment.  
9-007.02B2a The hospital must provide separate central sterile processing and waste processing areas.  
9-007.02B2b In new construction and where provided, central processing areas must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The hospital must have handwashing sinks in both clean and soiled rooms. |
| Nevada | HAPETER 449. MEDICAL AND OTHER RELATED FACILITIES HOSPITALS Policies and Procedures for Operation of Hospital NAC 449.327 (2014) | 1. To meet the ongoing needs of its patients, a hospital shall:  
(a) Provide a designated area for the preparation, sterilization and storage of sufficient sterile supplies and medical and surgical equipment; and  
(b) Dispense the sterile supplies and equipment to all departments, units and services within the hospital.  
2. A hospital which prepares, sterilizes and stores its supplies and equipment directly shall develop systems and standards that are consistent with:  
(a) The standards for the control of infection established by the infection control officer of the hospital;  
(b) The standards developed by the Occupational Safety and Health Administration for the preparation, sterilization and storage of such supplies and equipment; and  
(c) When applicable, the manufacturer’s guidelines for the use and maintenance of the equipment.  
3. If the supplies and equipment are sterilized on the premises of a hospital, the process of sterilization must be supervised by a person who has received specialized training in the operation of the process of sterilization, including training in methods of testing the process to verify the efficiency of the process of sterilization. |
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<th>State</th>
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<td>New Hampshire</td>
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<td>New Mexico</td>
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| New York   | TITLE 10. DEPARTMENT OF HEALTH CHAPTER V. MEDICAL FACILITIES SUBCHAPTER A. MEDICAL FACILITIES--MINIMUM STANDARDS ARTICLE 2. HOSPITALS PART 405. HOSPITALS--MINIMUM STANDARDS 10 NYCRR § 405.24 (2014) § 405.24 Environmental health | The hospital shall be operated and maintained to ensure the safety of patients.  
(i) Central supply services. The hospital shall ensure the provision of central supply services for the preparation, storage, handling and distribution of sterile supplies and other patient care items. The hospital shall conform to current, acceptable standards of practice for central services.  
(1) Central services shall be under the direction of an individual qualified by education, training and experience to supervise the personnel and functions of central services, and who shall be responsible to the chief executive officer either directly, or through a designated department head.  
(2) Central services shall be evaluated as part of the hospital's ongoing quality assurance program.  
(3) The functional design and workflow patterns in central services shall provide for the separation of soiled and contaminated supplies from those that are clean and sterile.  
(4) There shall be written policies and procedures for the decontamination and sterilization activities performed in central services and elsewhere in the hospital, and for related requirements. These policies and procedures shall include, but not be limited to provisions for:  
(i) the decontamination, cleaning, preparation and sterilization of patient care supplies and equipment; |
|   | (ii) the separation of soiled or contaminated supplies and equipment from clean and sterilized supplies and equipment;  
|   | (iii) the assembly, wrapping, storage, handling and distribution of sterile supplies and equipment in central services and all other areas of the hospital as applicable;  
|   | (iv) requirements for aeration of gas-sterilized items;  
|   | (v) maintaining and recording time and temperature for each sterilization cycle and aeration cycle, if any, with provisions for records to be kept at least one year;  
|   | (vi) the labeling of each sterilized item with the date sterilized, cycle and expiration date indicating the shelf life of the sterilized item if the hospital chooses to use time-related sterility criteria with established expiration dating of in-house reprocessed and sterilized supplies and equipment;  
|   | (vii) event-related sterility assurance if the hospital chooses to use such criteria for sterility assurance. Such sterility assurance shall:  
|   |   (a) comply with generally accepted standards for sterility assurance such as those endorsed by the Association for the Advancement of Medical Instrumentation, the Joint Commission on the Accreditation of Healthcare Organizations or other such entities recognized as appropriate by the Commissioner;  
|   |   (b) be based on the results of an evaluation of current hospital policies and procedures for handling sterile supplies;  
|   |   (c) be reflected in the hospital's written policies which detail the process and responsibilities and which have been approved by the infection control officer and Infection Control Committee, if any;  
|   |   (d) be addressed through inservice education of staff; and  
|   |   (e) provide for quality assurance monitoring to evaluate effectiveness;  
|   | (viii) the use of chemical indicators with each cycle and weekly bacteriological spore monitoring for all sterilizers |
(ix) the rotation and reprocessing of sterile equipment and supplies; and
(x) the routine checking and removal of outdated or damaged sterile supplies and
equipment or supplies or equipment which no longer meet the sterility standards of the
event-related sterility assurance criteria and the recall of such supplies and equipment
from all areas of the hospital.

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<th>State</th>
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<td>North Dakota</td>
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<td>Ohio</td>
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| Oklahoma       | TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
                CHAPTER 667. HOSPITAL STANDARDS
                SUBCHAPTER 25. SURGICAL SERVICES
                310:667-25-1 Department of surgery |

(15) The service shall be responsible for central sterile supply and shall adhere to the following:

(A) Sterilization equipment shall be provided which is adequate to properly sterilize the
instruments and other supplies.

(B) Chemical, biological, and mechanical process indicators appropriate to the type of
sterilizer shall be used to indicate items have been subjected to sterilization conditions. A
sterilization process indicator shall be placed within each package to be sterilized. If
the internal process indicator is not visible from the outside of the package, a separate
indicator should be used on the outside of the package.

(C) Equipment for all sterilization methods shall be used, maintained, and monitored
according to the manufacturer's written instructions. Sterilized items and packages shall
be cooled, aerated, rinsed, dried, or otherwise handled according to the method of
sterilization and manufacturer's instructions after sterilization.
(D) Each facility shall establish policies and procedures which describe the interval(s) during which sterile items are considered to remain sterile. Such policies may be event-related or time-related. Policies for event-related shelf life labeling shall take into consideration environmental sources of contamination, barrier properties of packaging materials, storage and distribution practices, inventory control, and frequency of handling between distributor and the user. Inventory control practices shall include a requirement that stock be rotated on a first in, first out basis and a lot control system shall be established to allow for traceability of the contents of each sterilized load in the event of a sterilizer failure or malfunction.

(E) Written or graphic records shall be maintained for each operation of the sterilizer, showing mechanical monitoring of temperature, exposure time, pressure, humidity, chemical concentrations, and/or air removal as appropriate. Records shall also include the date and time for each operation, with other pertinent data, and the signature of the operator of the sterilizer.

(F) Periodic bacteriological testing of sterilizer performance shall be conducted at least weekly using a biologic indicator appropriate to the type of sterilizer and as recommended by the manufacturer. The results of all biological indicator tests shall be interpreted by qualified individuals in accordance with the manufacturer's instructions. Records of biological indicator testing shall include at least the date and time of the test, the identity of the sterilizer used, the test result, the identity of the individual interpreting the test, and a description of any corrective actions taken as a result of the test.

(G) Written policies and procedures shall be established and followed for the recall of reprocessed items in the event of a sterilization failure.
<table>
<thead>
<tr>
<th>Oregon</th>
<th>CHAPTER 331 OREGON HEALTH LICENSING AGENCY DIVISION 420 PRACTICE STANDARDS</th>
<th>331-420-0020 Approved Sterilization and Disinfection Standards</th>
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<tbody>
<tr>
<td></td>
<td>(1) New gloves must be worn during any disinfection or sterilization procedure.</td>
<td>(2) The disinfection or sterilization process listed in subsection (4) or (5) of this rule is not required if disinfected or sterilized single-use prepackaged instruments, obtained from suppliers or manufacturers are used.</td>
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<td>(3) All reusable instruments that come in direct contact with a client's skin or are exposed to blood or other potentially infectious materials must be disinfected or sterilized before use on a client or re-used on another client in accordance with subsection (4) or (5) of this rule.</td>
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<td>(4) Approved cleaning and disinfection process for reusable instruments includes the following ordered method:</td>
<td>(5) Approved cleaning and sterilization process for reusable instruments includes the following ordered method:</td>
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<td>(a) Clean reusable instruments by manually brushing or swabbing visible foreign matter and rinsing the instruments with warm water and an appropriate detergent solution to remove blood and other potentially infectious materials;</td>
<td>(a) Clean reusable instruments by manually brushing or swabbing visible foreign matter and rinsing the instruments with warm water and an appropriate detergent solution to remove blood and other potentially infectious materials;</td>
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<td>(b) Immerse reusable instruments in a high level disinfectant defined under OAR 331-405-0020 and labeled accordingly; and</td>
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<td>(c) Store disinfected instruments in a dry, disinfected, closed cabinet or other tightly-covered container reserved for the storage of disinfected instruments.</td>
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(b) Individually package reusable instruments using sterilization pouches that include a color indicator strip to assure sufficient temperature during each sterilization cycle. The date the sterilization was performed must be applied to the sterilization pouch;

(c) Place individually packaged reusable instruments in an autoclave sterilizer (steam or chemical), or dry heat sterilizer registered and listed with the Food and Drug Administration; and

(d) Store sterilized instruments individually packaged in a dry, disinfected, closed cabinet or other tightly-covered container reserved for the storage of sterilized instruments.

(6) As of July 1, 2014 all denturists are required to sterilize all reusable instruments by use of a dry heat or steam autoclave. All instruments that are not reusable and sterilized must be disposed of in an appropriate manner.

(7) If a denturist is using an autoclave or dry heat sterilizer under subsection (5) of this rule the denturist must have the autoclave or dry heat sterilizer biologically tested monthly (spore testing) verified through an independent laboratory, to assure all microorganisms have been destroyed and sterilization achieved. Biological spore test results must be immediately available at all times for inspection by the Agency and kept at facility premises for a minimum of two years.

(8) If a denturist is using an autoclave or dry heat sterilizer under subsection (5) of this rule they must ensure the entire device is cleaned and maintained in accordance with manufacturer's instructions and a copy of the manufacturer's recommended procedures for the operation of the device must be kept on file at the business premise.

(9) The expiration date for sterilized reusable instruments under subsection (5) of this rule is one year from the date of sterilization unless the integrity of the package is
compromised.

(10) All surfaces that may be contaminated by blood or other potentially infectious materials must be disinfected with a high-level disinfectant defined under OAR 331-405-0020 and is labeled accordingly.

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<th>Pennsylvania</th>
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<td>TITLE 28. HEALTH AND SAFETY</td>
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<td>PART IV. HEALTH FACILITIES</td>
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<td>SUBPART B. GENERAL AND SPECIAL HOSPITALS</td>
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<td>CHAPTER 149. CENTRAL SUPPLY SERVICES</td>
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§ 149.1. Principle
Central supply service functions shall be effectively organized, directed and staffed by qualified personnel.

§ 149.2. Director
The person in charge of central supply services shall be qualified by education, training, or experience in the intended purposes of this department. He shall participate in the development of the departmental policies, procedures, and training programs, shall supervise, schedule and assign responsibilities to personnel, and shall maintain communication with other department heads in the hospital.

§ 149.3. Facilities
The hospital shall have a central supply service physically separated from other areas. Central supply service shall be provided with facilities to process, sterilize, store, and dispense supplies and equipment.

§ 149.11. Availability of supplies and equipment
The hospital shall have an effective written plan for the availability of all necessary materials, equipment and supplies.

§ 149.12. Handling of equipment
All hospital employees using sterile supplies shall be advised of sterilization controls, rotation schedules for stored equipment, appropriate and proper use of all sterile equipment, and methods for handling and returning contaminated materials.
§ 149.13. Prevention of transmission of pathogens
There shall be written policies and procedures to prevent indirect and direct transmission of pathogens or other toxic substances with materials issued from the central supply service.

§ 149.14. Central supply service education program
Although initial orientation of employees in the central supply service should be sufficient to enable them to carry out the tasks outlined in their job descriptions, they should have further on-the-job training and continuing education in the areas of asepsis and other pertinent topics applicable to the services rendered by the service.

§ 149.15. Reference material
Current reference manuals, pamphlets, journals, and books, as well as information and scientific data from manufacturers concerning their products and equipment, should be made available for reference and guidance of central supply service personnel and potential users of the equipment and supplies.

Rhode Island

AGENCY 14.
DEPARTMENT OF HEALTH
SUB-AGENCY 090.
HEALTH FACILITIES, LICENSURE, CONSTRUCTION
CHAPTER 007. LICENSING OF HOSPITALS
CRIR 14-090-007 (2014)
14 090 007. LICENSING OF HOSPITALS

Section 21.0 Central Service Functions.

21.1 Hospitals with central service functions shall operate, under the supervision of a qualified person, a central service for the processing, sterilization, storing and dispensing of clean and sterile supplies and equipment.

21.2 Adequate facilities shall be provided for the cleaning, preparation, sterilization, aeration, storage and dispensing of supplies and equipment for patient care.

21.3 Areas for the processing of clean and dirty supplies and equipment shall be separated by physical barriers.

21.4 Written procedures shall be established for all central service functions including:
a) procedures for all sterilization and for monitoring the effectiveness thereof; and b)
appropriate disposal of wastes and contaminated supplies; and c) compliance with the provisions of reference 9.

21.4.1 Such procedures shall be subject to the approval of a multidisciplinary hospital group.

21.5 Reports of bacteriological tests and dated recordings of thermometer charts and inspection records shall be maintained in accordance with written procedures.

21.6 Central service procedures shall apply wherever sterilization is performed.

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<tr>
<th>South Carolina</th>
<th>38-6 S.C. Reg. 191</th>
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<tr>
<td>SOUTH CAROLINA REGISTER</td>
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<td>ISSUE: Volume 38, Number 6</td>
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1208. Central Supply. (I)

A. The department head shall be qualified for the position by education, training and experience as determined by the hospital policies and procedures. (II)

B. The number of supervisory and other personnel shall be related to the scope of the services provided. (II)

C. There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the hospital. These policies and procedures shall relate, but are not limited to the following:

1. 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.

2. Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate
the sterilization equipment used for each item, including the sterilization date and cycle.

D. A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc., should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.

E. Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

F. All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

G. Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

SECTION 605. CENTRAL SUPPLY

605.1 Personnel:

A. The department head shall be qualified for the position by education, training and experience.
B. The number of supervisory and other personnel shall be related to the scope of the services provided.

605.2 Policies and Procedures:

There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the hospital. These policies and procedures shall relate, but are not limited to the following:

1. 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.

2. Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

605.3 Controls:

A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc. should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.
605.4 Storage:

Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

606.5 Containers and Packages:

All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

605.6 Outdated Supplies:

Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

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<tr>
<th>State</th>
<th>Rules</th>
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<tr>
<td>Tennessee</td>
<td>RULES OF THE TENNESSEE DEPARTMENT OF HEALTH, DEPARTMENT OF ENVIRONMENT AND CONSERVATION, AND DEPARTMENT OF FINANCE AND ADMINISTRATION BUREAU OF HEALTH LICENSURE AND REGULATION; DIVISION OF HEALTH CARE</td>
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<td>(k) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:</td>
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<td>1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;</td>
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<td>2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;</td>
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<td>3. Proper utilization of sterilization process monitors, including temperature and</td>
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| Texas | TITLE 25. HEALTH SERVICES  
PART 1. DEPARTMENT OF STATE HEALTH SERVICES  
CHAPTER 133. HOSPITAL LICENSING SUBCHAPTER C. OPERATIONAL REQUIREMENTS  
25 TAC § 133.41 (2014)  
§ 133.41. Hospital Functions and Services | FACILITIES; BOARD FOR LICENSING HEALTH CARE FACILITIES | pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and  
4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;  
5. Procedures for recall and disposal or reprocessing of sterile supplies; and  
6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.  
(v) Sterilization and sterile supplies.  
(1) Supervision. The sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training and experience. Staff responsible for the sterilization of supplies and equipment shall participate in a documented continuing education program; new employees shall receive initial orientation and on-the-job training.  
(2) Equipment and procedures.  
(A) Sterilization. Every hospital shall provide equipment adequate for sterilization of supplies and equipment as needed. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of the various materials required.  
(B) Written policy. Written policies and procedures for the decontamination and sterilization activities performed shall be adopted, implemented and enforced. Policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing and |
sterilization of reusable items, as well as those for the assembly, wrapping, storage, distribution and quality control of sterile items and equipment. These written policies shall be reviewed at least every other year and approved by the infection control practitioner or committee.

(C) Separation. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, 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. Hand washing facilities shall be provided and a separate sink shall be provided for safe disposal of liquid waste.

(D) Labeling. All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Those which are sterilized by the hospital shall be labeled so as to be identifiable both before and after sterilization. Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(E) Preparation for sterilization. (i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment. (ii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(F) Packaging. All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized.

(G) External chemical indicators. (i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process. (ii) The indicator results shall be interpreted according to manufacturer's
written instructions and indicator reaction specifications. (iii) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(H) Biological indicators. Biological indicators are commercially-available microorganisms (e.g., United States Food and Drug Administration (FDA) approved strips or vials of Bacillus species endospores) which can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes). (i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used. (ii) Biological indicators shall be included in at least one run each week of use for steam sterilizers, at least one run each day of use for low-temperature hydrogen peroxide gas sterilizers, and every load for ethylene oxide (EO) sterilizers. (iii) Biological indicators shall be included in every load that contains implantable objects. (iv) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load. (v) If a test is positive, the sterilizer shall immediately be taken out of service.

(I) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(II) All available items shall be recalled and reprocessed if a sterilizer malfunction is found and a list of those items not retrieved in the recall shall be submitted to infection control.

(III) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(I) Sterilizers. (i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions. (ii) EO sterilizers shall be used for processing
heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions. (iii) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(J) Disinfection. (i) Written policies, approved by the infection control committee, shall be adopted, implemented and enforced for the use of chemical disinfectants. (ii) The manufacturer's written instructions for the use of disinfectants shall be followed. (iii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use. (iv) Disinfectant solutions shall be kept covered and used in well-ventilated areas. (v) Chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" may be used either for sterilization or high-level disinfection. (vi) All staff personnel using chemical disinfectants shall have received training on their use.

(K) Performance records. (i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of five years. (ii) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(I) the sterilizer identification;

(II) sterilization date;

(III) cycle number;

(IV) contents of each load;

(V) duration and temperature of exposure phase (if not provided on sterilizer recording charts);
(VI) identification of operator(s);

(VII) results of biological tests and dates performed;

(VIII) time-temperature recording charts from each sterilizer;

(IX) gas concentration and relative humidity (if applicable); and

(X) any other test results.

L Storage of sterilized items. (i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage. (ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity. (iii) The hospital shall adopt, implement and enforce a policy which describes the mechanism used to determine the shelf life of sterilized packages.

(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual adopted, implemented and enforced policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review.

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<tr>
<th>Utah</th>
<th>HEALTH R432. FAMILY HEALTH AND PREPAREDNESS, LICENSING. R432-100. GENERAL HOSPITAL STANDARDS. U.A.C. R432-100-34</th>
<th>R432-100-34. Central Supply Services.</th>
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<td></td>
<td>(1) The central supply service supervisor shall be qualified for the position by education, training, and experience.</td>
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<td>(2) The hospital shall provide space and equipment for the cleaning, disinfecting, packaging, sterilizing, storing, and distributing of medical and surgical patient care supplies.</td>
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(a) A hospital central service area shall provide for the following:

(i) A decontamination area which shall be separated by a barrier or divider to allow the receiving, cleaning, and disinfection functions to be performed separately from all other central service functions;

(ii) A linen assembly or pack-making area which shall have ventilation to control lint. The linen assembly or pack-making area shall be separated from the general sterilization and processing area.

(iii) The sterilization area shall contain hospital sterilizers with approved controls and safety features.

(b) The accuracy of the sterilizers' performance shall be checked by a method that includes a permanent record of each run.

(c) Sterilizers shall be tested by biological monitors at least weekly.

(d) If gas sterilizers are used, they shall be inspected, maintained, and operated in accordance with the manufacturer's recommendations.

(3) The storage area shall be separated into sterile and non-sterile areas. The storage area shall have temperature and humidity controls, and shall be free of excessive moisture and dust. Outside shipping cartons shall not be stored in this area.

(4) During each shift that the central service area is staffed, counter tops and tables shall be wiped with a broad spectrum disinfectant.

(5) All apparel worn in central supply shall be issued and laundered according to hospital policy.
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<th>State</th>
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<th>Regulations</th>
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| Vermont   | AGENCY 13. AGENCY OF HUMAN SERVICES SUB-AGENCY 140. DEPARTMENT OF HEALTH CHAPTER 019. HOSPITAL LICENSING PROCEDURE CVR 13-140-019 (2014) 3-140 019. Hospital Licensing Procedure | 3-947. --Sterilizing  
(a) Sterilizers and autoclaves shall be provided of the required types and necessary capacity to adequately sterilize instruments, utensils, dressings, water, operating room material such as gloves, sutures, etc., and as required for laboratories. The sterilizers shall be recognized hospital types with approved controls and safety features.  
(b) Bed pans, urinals, wash basins, mouthwash cups, drinking glasses, and any other containers for individual use shall be sterilized on the patient's discharge from the hospital.  
(c) The hospitals shall arrange adequate procedures for checking sterilization.  
(d) Sterile equipment and supplies shall be suitably stored separately from unsterile material.  
3-963. Surgical and adjunct services -- Surgical facilities  
(c) There shall be facilities for sterilizing, scrubbing, and cleanup. Such facilities should not be located within a major operating room. There should be adequate storage space for sterile supplies, instruments and medications. |
| Virginia  | NONE      |                                                                              |
| Washington| NONE      |                                                                              |
### West Virginia

**TITLE 64. LEGISLATIVE RULE**
**WEST VIRGINIA STATE BOARD OF HEALTH SERIES 12. HOSPITAL LICENSURE**

W. Va. CSR § 64-12-6 (2014)

§ 64-12-6. Operational Services.

**6.5. Central Sterilization and Supply**

6.5.a. The hospital shall provide for the decontamination and sterilization of reusable equipment and supplies for all areas of the hospital.

6.5.b. If the hospital practices in-house sterilization, it shall have a central sterilizing and supply room to prepare, sterilize, store, and dispense sufficient sterile supplies and equipment to all units of the hospital.

6.5.c. The hospital shall have policies and procedures, using acceptable clinical standards, for the decontamination and reprocessing of supplies.

6.5.d. A cabinet or other suitable enclosed space shall be provided for storing sterile equipment and supplies in a convenient and orderly manner.

### Wisconsin

**SAFETY AND PROFESSIONAL SERVICES CHAPTER SPS 72 SAFE PRACTICE**

Wis. Adm. Code SPS 72.02

**SPS 72.02 Sterilization**

(1) All nondisposable needles, acupuncture equipment that comes in contact with a patient's blood or body fluids or penetrates the skin, and equipment used to handle or store needles shall be sterilized after each use.

(2) All equipment required to be sterilized by this section shall be thoroughly wiped clean with a disinfectant or cleansing solution before sterilization.

(3) Sterilization, as required by this section, shall be accomplished by use of one of the following in accordance with manufacturer's instructions:

(a) Autoclave for 30 minutes at 250 [degrees] F., 15 pounds of steam pressure. If this method is employed, the packaging used to store the needles shall have autoclave tape to verify sterilization.

(b) Dry heat sterilization for 2 hours at 338 [degrees] F. If this method is employed, the
<table>
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<th>Wyoming</th>
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acupuncturist shall check needles for breakage after sterilization.
(c) Ethylene oxide.

(4) The following procedures are not acceptable methods of sterilization:

(a) Boiling.
(b) Soaking in alcohol or other antiseptic solution.
(c) Glass bead sterilizer.

(5) Equipment used to sterilize shall be maintained in good working order. Sterilization equipment shall be monitored as required by the manufacturer to ensure that it is functioning in accordance with manufacturer's specifications.

(6) Any equipment that has been sterilized shall be stored in packaging that protects against contamination and that is clearly marked to distinguish it from unsterile equipment. Sealed packages containing sterilized equipment shall be marked with an expiration date in accordance with the manufacturer's recommendations.

(7) Resterilization of equipment is required if any of the following occur:

(a) It is equipment stored in a sealed package beyond its expiration date.

(b) Its packaging is damaged in any way which adversely affects the ability of the packaging to maintain the sterility of its contents.

(c) It is not used on the day the equipment is removed from its package.

(8) No needle, cup, or other device shall be used on more than one point of any patient, or applied to a single point on any patient more than one time, before it is resterilized.