PURPOSE

To provide procedure on how to sterilize and disinfect equipment.

POLICY

Medical devices or instruments that require sterilization or disinfection must be thoroughly cleaned before packaged for the sterilizer or exposure to the germicide. The manufacturer’s specifications for compatibility of the medical device with chemical germicides shall be followed.

Facilities that do not have an infirmary or high level of care shall not operate sterilizers in the medical area. These units shall perform only minor invasive procedures (incision and drainage of minor abscess, injections, etc.) Only disposable equipment shall be used for such procedures. Inmates requiring a higher level of medical care shall be referred to a facility capable of performing the level of care required.

DEFINITIONS

Sterilization - A process by which all forms of microbial life including bacteria, viruses, spores, and fungi are destroyed. Instruments or devices that enter sterile tissue or the vascular system of any inmate or through which blood flows must be sterilized before use.

High-level disinfection - a procedure that kills vegetative organisms and viruses, but not necessarily large numbers of bacterial spores. Devices that contact mucous membranes must be sterilized or receive high-level disinfection before use. Chemical germicides that are registered with the U.S. Environmental Protective Agency (EPA) as “sterilants” may be used either for sterilization or for high-level disinfection depending on contact time. Manufacturer’s directions must be followed when using these products for disinfection.

PROCEDURE

Facilities with medical areas that operate sterilizers shall follow the following procedures:

1. Cleaning of Equipment and Instruments to be Sterilized - Soiled equipment and instruments must be thoroughly cleaned before sterilization. An enzymatic detergent should be used. Do not use disinfectant solution as this binds protein to the equipment. There must be a designated area for cleaning and packaging instruments. Counter tops where instruments are packaged must be kept clean and wiped down at least daily with an EPA registered germicidal solution.

2. Packaging of Instruments for Sterilization - Each package must be labeled with the date processed and must have a chemical indicator strip placed inside. The package will be sealed with steam or ethylene oxide pressure sensitive tape as appropriate.

3. Biological Monitoring of Sterilizers

   a. Sterilizers will be tested at least once a week with a biological indicator. For steam sterilizers, Bacillus stearothermophilus, shall be used. For ethylene oxide (gas) sterilizers, B. atropheus (formerly known Bacillus subtilis), shall be used.
b. If a positive biological indicator is detected the sterilizer shall not be used again until it has been repaired.

c. Any equipment or unused instruments processed since the last negative biological indicator test must be re-processed.

4. There must be one employee assigned the responsibility of keeping detailed maintenance and monitoring records of the sterilizer.

5. Sterile supplies must be stored in clean cabinets. Cabinets must be cleaned at least monthly with an EPA registered germicidal solution.

6. Expiration dates must be checked once each week. The shelf life of unopened or undamaged packaged sterile items are:

   a. Double thickness muslin wrapped items are considered sterile for thirty days.
   b. Double thickness muslin wrapped items placed in plastic sealed dust covers are considered sterile for twelve months.
   c. Items sealed in plastic wrap are considered sterile for twelve months.

7. Preventive maintenance and performance verification records:

   a. The staff member responsible for the maintenance log will insure and document weekly cleaning of the sterilizer inside and out with a mild soap and water solution.
   b. Each load or item will be monitored by a chemical indicator strip.
   c. The sterilizer will be monitored at least weekly using the appropriate biological monitor. A record of the biological monitoring will be kept where the sterilizer is maintained. Repair and maintenance will also be recorded.
   d. The responsible staff member will maintain a log that identifies each load and includes the exposure time, temperature, and identifies the operator by name.

8. Equipment that has been contaminated with blood or other body fluids must be decontaminated and cleaned before being repaired. If part of the equipment cannot be decontaminated prior to servicing or shipping for repair, a BIOHAZARD tag must be attached listing which parts are contaminated and prepare a memorandum listing the contaminated parts and why decontamination is not feasible. A copy of the memo must be provided to all employees, service representatives, manufacturers, or persons handling the equipment as appropriate.

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