DEPARTMENT OF THE ARMY TECHNICAL BULLETIN

STERILIZING MEDICAL, SURGICAL, DENTAL, AND VETERINARY MATERIEL

Headquarters, Department of the Army, Washington, DC
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Section I Introduction

1. Purpose.

This bulletin prescribes policies, responsibilities, and methods for the sterilization process within the Department of the Army health care facilities. It covers processing, sterilizing, handling, and storing of medical, surgical, dental, and veterinary materiel before, during, and after sterilization. The objective of this bulletin is to achieve assurance of sterility and delivery of sterile supplies to user areas of health care facilities. Sanitizers (formerly identified as sterilizers-boiling type), pasteurizers, and automated chemical disinfection processors are not sterilizers; they will not be used for this purpose. The methodology for evaluation and selection of equipment and installation requirement-s for sterile processing will not be covered in this bulletin.

2. References

a. Required publications.

(1) AR 40-66 (Medical Record and Quality Assurance Administration). Cited in paragraph 12.

(2) AR 25-400-2 (The Modern Army Recordkeeping System (MARKS)). Cited in paragraphs ***7b(5), 8b(3),*** and 10.

(3) FM 8-38 (Centralized Materiel ServicelSection). Cited in paragraph ***4b(4).***

b. Referenced form.

DA Form 4106 (Report of Unusual Occurrence).

3. Explanation of **abbreviations and terms**

Abbreviations and special terms used in this bulletin are explained in the glossary.

4. Responsibilities

a. Commanders of medical treatment facilities (MTFs), dental activities, and veterinary activities will ensure compliance with policies stated in paragraphs 5 through 12.

b. Supervisors of the sterilization process will ensure that personnel performing the sterilization tasks have-

(1) Documented formal training.

(2) Orientation.
(3) On-the-job training.
(4) Active participation in continuing education or inservice programs. Specific guidelines for procedural implementation are found in FM 8-38.

Section II Processing of Supplies

5. Cleaning and packaging

a. Cleaning.

(1) Since a diminished bioburden increases the assurance that an item will be sterilized, thorough cleaning procedures are essential during the presterilization processing.

(2) Cleaning procedures will be carried out in a properly designed area of a centralized materiel services/section (CMS). This area will have a physical barrier separating it from all other areas of the department; it will be equipped for cleaning procedures. Facilities that do not have a central processing department must designate an area for this function.

b. Packaging.

(1) The function of a package containing a sterile medical item is to assure that the contents are maintained in a sterile condition until the package is intentionally opened; provisions must be made for the contents to be removed without contamination.

(2) Users must evaluate the many packaging materials available and select those best suited to their needs. Packaging material of reuseable woven fabrics must be laundered between uses. Factors to be considered include-

(a) Suitability for the sterilization method used. The material must provide for adequate air removal and sterilant penetration.

(b) Adequacy of barrier to microorganisms or their vehicles.

(c) Resistance to tear or puncture.

(d) Proven seal integrity.

(e) Ease of aseptic presentation. The package must be flexible and memory free.

(f) Absence of toxic ingredients and nonfast dyes.

(g) Economy.

6. Sterilizing equipment

Saturated steam under pressure, dry heat, or gas will be used within the Army Medical Department to sterilize supplies and equipment. These items are used in patient care where sterility is essential. Saturated steam under pressure is the preferred method of sterilization for all medical materiel except as indicated in paragraphs 9c and ***d*** or unless not recommended by the materiel manufacturer. The methods of sterilization are steam, chemical, and dry heat.

a. Steam.

(1) Users must have a basic understanding of the operations of the types of sterilizers being used in the facility.

(2) Types of steam sterilizers include-

(a) Gravity displacement, general purpose, and hi-speed emergency.

(b) Prevacuum.

(c) Vacuum pulsing.

b. Chemical.

(1) ***Ethylene oxide (EO).***

(a) EO is the choice method for sterilization of heat-labile and moisture-sensitive medical items, supplies, and equipment.

(b) Because of its toxic, potentially flammable and explosive nature, EO must be used with caution. Users must have a basic understanding of EO system hardware and potential sources of EO release to the environment. Efforts should be directed toward decreasing atmospheric levels in the worker environment and residual levels in sterilized devices. The latest guidelines for the safe use of EO must be implemented.

(c) All EO sterilized items are to be aerated in a mechanical aerator. Manufacturers of medical devices must provide in writing the sterilization and aeration instructions to be followed when their products are not sterile, but are required to be EO sterilized in the facility prior to use.

(2) Formaldehyde. Sterilization by formaldehyde should be done with caution due to its toxic properties. It is not recommended as a primary method of sterilization.

c. Dry heat. Dry heat may be used for the sterilization of anhydrous oils, greases, and powders.

7. Sterilization process monitoring

a. ***Chemical monitors.***

(1) Chemical monitors are physical or chemical devices employed to monitor one or more sterilization process parameters to detect failures in packaging, loading, andlor sterilizer function.

(2) Since there are presently no official performance standards for chemical monitors available, users are advised of the following:

(a) Selection should be based on reliability, safety, efficacy, and cost effectiveness.

(b) Users will require manufacturers of chemical monitors to provide written instructions to interpret indicator results and safety and performance characteristics of the sterilization process monitor.

(c) A chemical monitor will be considered an adjunct to a sound biological monitor, not a replacement for it.

(3) A chemical monitor must be used with every package processed.

b. Biological testing.

(1) The purpose of biological monitoring is to document the effectiveness of specific sterilization cycles under conditions of use.

(2) A biological test will be done a minimum of once weekly on dry heat sterilizers and on each type of steam sterilizer. A biological test will be done. with every EO load. When sterilizing solutions, a biological test suitable for liquids must be done with every load.

(3) Bacillus stearothermophilus spores will be used to test steam sterilizers. Bacillus subtilis spores will be used to test dry heat and EO sterilizers.

(4) Laboratories that perform biological testing will report any positive readings after 24, 48, and 72 hours of incubation; they will submit a final written report to the sterilizer user.

(5) Biological test results will be kept on file in the using area for a minimum of 12 months. MTFs inspected by the Joint Commission on Accreditation of Hospitals (JCAH) will keep results from one inspection to the next. (See AR 25-400-2.)

c. Load control and expiration identification.

(1) All supplies subjected to a sterilizing cycle will bear an identification load control number after completion of the sterilization process. (Ink, pencil, or stamped information on woven wrapping material is not recommended.) EO sterilized supplies will be identified with the load control number after completion of the aeration cycle. The local control number will consist of seven digits as follows:

(a) The first two digits indicate the numerical designation of each sterilizer.

(b) The third, fourth, and fifth digits indicate the calendar day of the year; for example, 001 through 365 days.

(c) The sixth and seventh digits indicate the number of the sterilization cycle during the 24-hour period.

(2) All packages will be marked visibly with an expiration date. (See para 9.)

(3) Color coding systems may be used only as an adjunct to the required expiration date and load control number.

(4) A log book will be maintained with the following information:

(a) Load control number.

(b) Expiration date.

(c) Contents of load.

(d) Operator.

8. Equipment monitoring

a. ***Bowie Dick type test for prevacuum and vacuum pulsing sterilizers.*** A Bowie Dick test will be run on prevacuum and vacuum pulsing type steam sterilizers each day of use. This test will test steam penetration by demonstrating the adequacy of air removal from the chamber and load, or the presence of an air leak.

b. Mechanical process control monitors.

(1) Mechanical process control monitors include time/temperature recording devices and temperature/pressure gauges. These must be examined by the sterilizer operator at the beginning and end of each sterilizer cycle. When time/temperature recorders are provided, the operator must be sure that the recording is marked with the date, load control number, and sterilizer identification. The operator must also ensure that the device is functioning properly. When time/temperature recorders are not provided, the operator will monitor the temperature/pressure gauges during the sterilization cycle to verify attainment of adequate temperature and duration of exposure.

(2) Before any materials are removed from the sterilizer, the sterilizer recording must be examined and initialed to verify attainment of adequate temperature and duration of exposure.

(3) Recordings -must be maintained in the using area with other sterilizer records for a minimum of 12 months. MTFs inspected by the JCAH will keep recordings from one inspection to the next. (See AR 25-400-2.)

9. Storage and inventory control of sterilized material

a. Shelf life. The shelf life of sterilized items is event-related and not time-related. It is dependent upon the quality of the wrapper material, the storage conditions, the conditions during transport, and the amount of handling. Shelf-life is not simply a matter of sterility maintenance, but is also a function of materials life and inventory control. However, for purposes of inventory control and inventory rotation, items will be packaged and dated in the following manner:

(1) Items transported from an environmentally controlled area, via covered or enclosed cart with a solid bottom shelf, to another environmentally controlled area with limited access and restricted traffic.

(a) Nonwoven, plastic, plastic/paper laminate -6 months.

(b) Papers and wovens-72 hours.

(c) Papers and wovens, placed in hermetically sealed or envelope-closure taped protective covers (after a sufficient cooling period following the sterilization cycle)-6 months.

(d) Papers and wovens removed from hermatically sealed or envelope-closure taped protective covers and not opened or contaminated-72 hours.

(e) Commercially prepared sterile items will be considered sterile unless the integrity of the packaging has been compromised or the manufacturer's expiration date has been reached.

(2) Items transported from an environmentally controlled area via open baskets, by hand, or open carts with perforated bottom shelf, to areas with poor or inadequate environmental conditions for storage and which do not have restricted traffic will be hermatically sealed or have envelope-closure of all packaged items and be dated for 6 months. Items removed from plastic and not used will be reprocessed.

(3) All plastic used either as primary packaging material or protective cover will meet medical grade plastic specifications; for example, 2 to 3 mils.

b. Sterile storage.

(1) Sterile materials should be stored at least 8 to 10 inches from the floor, at least 18 inches from the ceiling, and at least 2 inches from outside walls.

(2) Items should be positioned so that packaged items are not crushed, bent, compressed, or punctured.

(3) Items must not be stored in any location where they can become wet.

(4) Items should be stored on designated shelving, cabinets, or covered containers that are cleaned and maintained in a dry condition.

(5) Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas.

(6) Open shelved storage may be used in an environmentally controlled area with limited access and restricted traffic. Closed shelf storage will be used if conditions for open shelf storage are not met.

10. Maintenance and repair

Preventive maintenance and repair procedures must be outlined by the manufacturer of the sterilizer and carried out by a trained individual. Preventive maintenance and repair records must be maintained in accordance with AR 25-400-2.

11. Solutions

Preparation and sterilization of parenteral and irrigating liquids by health care facilities are discouraged. However, there may be instances where solutions must be processed in the health care facilities; for example, in emergency and field situations. In such instances, a quality assurance program must be implemented to assure sterility and nonpyrogenicity.

12. Reprocessing of single-use items

Single-use items will not be reprocessed andlor resterilized in the health care facility unless the manufacturer provides specific written instructions for processing and reusing these items. Only in emergency situations can single-use items be reprocessed for patient care use. This emergency situation must be well-documented. Use DA Form 4106 (Report of Unusual Occurrence). (See AR 40-66).

Glossary

Section. I Abbreviations

AOC
area of concentration
CMS
centralized materiel service
EO
ethylene oxide
JCAH
Joint Commission on Accreditation of Hospitals
MOS
military occupational specialty
MTF
medical treatment facility

Section II Terms

Bioburden (bioload, microbial load)
The number of microorganisms with which an object is contaminated.

Biological monitor
A calibration of microorganisms that has a high resistance to the mode of sterilization being monitored. It is in or on a carrier, put up in a package that maintains the integrity of the inoculated carrier, and is of convenience to the ultimate user. The biological monitor shows that sterilization conditions have been achieved. It is also known as a biological indicator or biological spore test.

Closed storage
Containers that are closed on all sides; for example, cabinets with doors, case carts, or modular enclosed cabinets.

Centralized materiel service/section
An organizational element of the nursing department in an MTF that is charged with the responsibility of processing supplies and equipment used in the treatment and care of patients.

Chemical monitors
Physical or chemical devices employed to monitor one or more parameters in a sterilization process in order to assure that factors such as product packaging, loading, and functioning of the equipment do not prevent sterilization.

Decontamination
The destruction or removal of living organisms to a safe level, but not necessarily to zero.

Hermetically
Description of an airtight seal that prevents contaminants from entering the wrapped or packaged item.

Memory-free
Descriptive terminology used in wrapping or packaging materiels to define the ease with which wrappers or packages are opened and which do not rebound to the folded position.

Open storage
Containers that are not closed on all sides; for example, open shelves or cabinets without doors.

Protective cover
A cover that provides protection from dust, dirt, and moisture during the storage period.

Restricted access areas (limited traffic area)
An isolated room or area dedicated to sterile supply storage that can be closed off from the main traffic corridors. Access is limited to authorized personnel appropriately attired in protective garb; for example, scrub suit, cap, mask, and shoe covers.

Sterilization process
A process that includes the collecting, receiving, sorting, decontamination, cleaning, preparation, packaging, sterilizing, dating, storing, inventory and issue of reuseable items.

Trained person
One who has specialized knowledge, skills, and training in all aspects of the sterilization process and has one of the following MOS' or AOC: MOS 91D, 91B, 91C, 35G, or 35U, or AOC 66E.

User area
An area where sterile supplies are being used; for example, ward, clinic, treatment area, or battalion aid station.

Suggested improvements. The proponent agency of this bulletin is the Office of The Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to HQDA (SGPS-CP-N), 5111 Leesburg Pike, Falls Church, VA 22041-3258.

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