Approved October 2008
Revised February 2015
Revised April 14, 2017

AST Guidelines for Best Practices in Monitoring Sterility

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organization's (HDO) reinforce best practices in monitoring sterility as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting (NBSTSA). The purpose of the Guidelines is to provide information OR supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures for monitoring sterility in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding monitoring sterilization practices per HDO protocols.

Rationale

A key principle of asepsis states all items (e.g., surgical instruments, equipment and supplies such as sponges, suture and needles) that are handled and used by the sterile team members, as well as those items that contact the patient's tissues are sterile to prevent surgical site infections (SSI).[1] The delivery of safe, quality patient care demands a team effort in establishing a sterile field to prevent SSIs. Guaranteeing the use of sterile items requires a quality control system that involves *physical monitoring* of the sterilizing machines, and *chemical and biological indicators* (CI and BI respectively) that CSTs rely upon to ensure the sterilization parameters have been met. Additionally, the use of indicators serves as an aid in pinpointing and resolving processing failures.

Evidence-based Research and Key Terms

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles. Additionally, the Guidelines are based upon the standards published by the Association for the Advancement of Medical Instrumentation (AAMI)

The key terms used for the research of the Guidelines include: biological indicator; chemical indicator; emulating indicator; ethylene oxide sterilization; external chemical indicator; implants; integrating indicator; internal chemical indicator; multi-variable indicator; physical monitoring; process challenge device; process indicator; process

monitoring device; single-variable indicator; steam sterilization. Key terms used in the Guidelines are italicized and included in the glossary.

Guideline I

A *process indicator,* Class 1 *external CI,* should be affixed to or printed on the outside of every HDO-assembled instrument tray, package, or rigid container that can be visualized by CSTs to confirm the sterilization processing conditions have been met, unless the *internal CI* is visible (e.g., peel pack with clear plastic on one side).[2-5]

1. The use of a Class 1 external CI is based upon compliance with ANSI/AAMI ST79:2010/A4:2013. (See Table A: Six Classes of CIs)
    A. Except for those packages that allow the CST to visualize the internal CI, such as a paper-plastic peel pack, an external CI should be used on all instrument trays, packages, or rigid containers (hereafter, all items will be referred to as "packages").
    B. Types of class I external CIs include sterilizer indicator tape, indicating label, indicating strips, or an indicating printed legend that are chemically impregnated.[2-5] Upon exposure to the sterilization process the chemical should have a visible change in color (referred to as the "endpoint" response) and the color should be even.[4]
        1) Commercial packages typically include an external, color-changing printed legend that should be clearly observable to the CST to interpret.[5]
    C. External CIs are used to demonstrate that packages have been exposed to the physical conditions of the sterilizer to distinguish between processed and unprocessed packages.[2,3] They do not prove that the enclosed items are sterile. In other words, CIs demonstrate that a package has been subjected to specific sterilization processing conditions.[2,3]
    D. External CIs assist in detecting potential sterilization failures. The use of CIs should be part of an overall quality assurance program that includes physical monitoring of the sterilization machines, and use of internal CIs and BIs.[2,3]
    E. CSTs should visualize the external CI, or internal CI within paper-plastic peel packs, prior to opening a package in the OR to confirm that it has been exposed to the sterilization process and the color change is even.
        1) If the CST interpretation of a CI suggests that the package was inadequately exposed to the sterilization processing conditions, the package should not be opened and returned to the Central Sterile Processing Department (CSPD) for reprocessing.
    F. External CIs should be used per manufacturer's instructions for use (IFU). The manufacturer is required to provide written IFU on the storage, handling, and use of external CIs.[2,5] The CST should know how external CIs are used and how to interpret them per the IFUs.[4]

Guideline II

An *internal CI* should be used within each HDO-assembled package to comply with ANSI/AAMI ST79:2010/A4:2013.[2-5]

1. It is recommended that the HDO use a Class 3, 4, 5, or 6 Class of internal CI.
    A. Internal CIs are used to demonstrate that packages have been exposed to the physical conditions of the sterilizer to distinguish between processed and unprocessed packages.[2,3] They do not prove that the enclosed items are sterile. In other words, CIs demonstrate that a package has been subjected to specific sterilization processing conditions.[2,3]
    B. Specific types of internal CIs may aid in the detection of specific sterilization machine malfunctions, e.g., air leaks, improper temperature, poor quality steam. The use of internal CIs should be part of an overall quality assurance program that includes physical monitoring of the sterilization machines, the use of external CIs and BIs.[2,3]
    C. Internal CIs cannot be retrieved and visualized without opening the package, thus they must be retrieved at the time the package is to be used.
        1) Internal CIs must be retrieved, visualized and interpreted by the CST during the time of preoperative case management (setting up the sterile back table and Mayo stand) to confirm that it has been exposed to the sterilization process and the color change is even. If the CSTs interpretation determines that the sterilization process has been inadequate, the contents of the package should be considered non-sterile and the package immediately removed from the sterile field.
        2) The CST will need to determine how much of the sterile field was possibly contaminated by the package. For example, if the package was a rigid container system resting on a single basin stand and the CST has not yet placed the inner tray of instruments on the sterile back table, the back table will not require to be "broken" down. Second example, a package of sterile linen towels is tossed onto the back table that may have touched other sterile items and therefore, the towels and other items are considered non-sterile. In this instance, the CST will need to use his/her judgment as well as knowledge of the principles of asepsis in determining the course of action. In all instances, the CST will need to change gloves since they are considered contaminated from handling non-sterile items.
        3) The CST should hand the non-sterile package to the circulator who should return it with the internal CI and load identification information to the CSPD for reprocessing.
        4) Internal CIs should be used per manufacturer's instructions for use (IFU). The manufacturer is required to provide written IFU on the storage, handling, and use of internal CIs.[2,5] The CST should know how internal CIs are used and how to interpret per the IFUs.[4]

Table A: Six Classes of CIs[2-5]

Indicator	Class	Description
Process Indicator (also referred to as external CI)	1	Intended for use with HDO sterilized containers, packages, and peel packs.
Specific Test Indicators	2	Example is the Bowie-Dick type of indicator.
Single-variable Indicator	3	Reacts to one of the critical parameters of sterilization. May be used to meet internal CI recommendation.
Multi-variable Indicator	4	Reacts to two or more of the critical parameters of sterilization. May be used to meet internal CI recommendation.
Integrating Indicator	5	Reacts to all critical parameters of sterilization. May be used to meet internal CI recommendation. Within a *process challenge device* (PCD), may be used to monitor nonimplant and implant containing sterilizer loads. The PCD must also contain a BI for loads containing *implants*.
Emulating indicator	6	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor all sterilizer loads.

Guideline III

Biological indicators (BI) should be used per the standards in ANSI/AAMI ST79:2010/A4:2013, ANSI/AAMI ST41:2008/(R)2012, and ANSI/AAMI/ISO 15882:2008/(R)2013.

1. BIs are the only sterilization *process monitoring device* that provides a direct measure of the lethality of the sterilization process.[2,3]
    A. BIs are used to confirm that the physical conditions for sterilization were achieved.
2. The BI selected by the HDO should contain spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) for *steam sterilization* and *Bacillus atrophaeus* for *ethylene oxide sterilization*.
    A. There are types of BIs that contain the spore and an enzyme-based early-readout capability.[2]
    B. BIs should be used per the manufacturer's written IFU. Manufacturer's are required to provide written instructions on the storage, handling, use, and interpretation of the incubation results. CSTs should know how BIs are used and how to interpret the incubation results per the IFU.[4]
3. BIs should be used within PCDs for routine monitoring of the sterilization process at least weekly; however, it is recommended that the monitoring should be every day the sterilizer is used.[2,3]
    A. A PCD may be a user-assembled challenge test pack or a commercially, available, disposable challenge test pack.
        1) The PCD user-assembled challenge test pack should be assembled per the directions provided in ANSI/AAMI ST79:2010/A4:2013 for steam PCD challenge test pack and ANSI/AAMI ST41:2008/(R)2012 for *ethylene oxide* (EtO) PCD challenge test pack.
    B. Every sterilization load that contains implants should be monitored with a PCD containing a BI.[2-4] The PCD should also contain a Class 5 integrating CI.[2-4] **(AAMI)**
        1) Even though Class 5 integrating CIs have been correlated to BIs, they don't contain spores and can't directly measure the lethality of the sterilization process. Therefore, the Class 5 integrating CIs cannot be used as the sole means of verifying sterilizer efficacy and reason for using a PCD that contains both a BI and Class 5 integrating CI.[2-4]
        2) The implants should be quarantined until the results of the BI testing are available and interpreted.[2-4] Releasing implants before the BI results are known is unacceptable and is the exception, not the rule.[4]
        3) In the instance implant(s) must be released on an emergency basis (e.g., need for orthopedic screw and plate set) prior to the BI results being available, the use of a Class 5 integrating CI provides additional information about the critical parameters of the sterilization process. The release of the implants must be documented as well as the documentation of the results of the Class 5 integrating CI. The BI results should also be documented as

routinely performed under normal circumstances. The documentation should include patient information to trace the release and use of the implants to the exact patient. Annex L of ANSI/AAMI ST79:2010/A4:2013 provides examples of an implant log and an exception form.

The surgery department and CSPD should have written policies and procedures (P&P) that define emergency situations when implants are released prior to the availability of the BI test results. The development of the P&Ps should involve the infection control officer, surgeon(s), and risk management.

Steps should be taken by the surgery department to resolve if implants are being released on a routine basis prior to the availability of the BI test results. For example, it could be a matter of the surgery department identifying they do not have enough screw and plate sets to accommodate the number of routine and emergency orthopedic procedures; therefore, the HDO may need to budget for and invest money into purchasing additional sets.

4. Positive BI results will initiate a recall of the items in the load that were processed in the specific sterilizer. All items since the last negative BI test should be considered non-sterile and the surgery personnel should assist in retrieving those items from the surgery department sterile storage to send back to the CSPD.[2-5]

Guideline IV

The surgery department should review the P&Ps regarding monitoring sterility on an annual basis.

1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management, and infection control officer, particularly when reviewing the P&Ps for the early release of implants prior to the BI results being available.
    A. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary), and who participated in the review process.
2. CSTs should be familiar with the P&Ps for monitoring sterility. The orientation of new employees should include reviewing the P&Ps.

Guideline V

CSTs should complete continuing education to remain current in their knowledge of monitoring sterility.[6]

1. CSTs are involved in the retrieval of CIs from sterile packages and therefore, should periodically complete continuing education in the reprocessing procedures, and the selection, use and interpretation of CIs.[4] The correct interpretation of the CI endpoint is vital to preventing patient-acquired SSIs.
2. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.[7]

3. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
    A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing monitoring sterility.
    B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
    C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
4. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
5. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

Competency Statements

Competency Statements	Measurable Criteria
1. CSTs are knowledgeable of the various types of sterilization processes. 2. CSTs have a high level of knowledge and skills to implement the principles of asepsis. 3. CSTs have the knowledge and skills to evaluate and interpret the results of BIs and CIs used for monitoring the sterility of hospital-assembled and sterilized packages.	1. Educational standards as established by the *Core Curriculum for Surgical Technology*.[8] 2. The didactic subjects of sterile technique and sterilization practices are included in a CAAHEP accredited surgical technology program. 3. Students demonstrate knowledge of monitoring sterility in the lab/mock OR and during clinical rotation. 6. CSTs complete continuing education to remain current in their knowledge and skills of sterilization practices including annual review of the policies and procedures of the surgery department.[6]

Glossary

Biological indicator (BI): Self-contained monitor that uses microbes in the spore stage that are highly resistant to the type of sterilization process that is being monitored.

Chemical indicator (CI): Commercially produced device that monitors the physical conditions of a sterilization cycle that consists of a sensitive ink dye that changes color.

Emulating indicator: Class 6 CI that changes color when exposed to certain critical variables including time, temperature, presence of sterilizing agent for a specified sterilization cycle.

Ethylene oxide sterilization (EtO): EtO is an alkylating chemical agent that disrupts the DNA of microorganisms that is used as a sterilizing agent.

External chemical indicator: A Class 1 processing indicator that is placed on the outside of a HDO-assembled package that indicates if the package has gone through a sterilization process.

Integrating indicator: Class 5 CI designed to reach their endpoint response when exposed to critical variables including time, temperature, and presence of sterilizing agent. Class 5 is used in conjunction with a BI. If the exposure temperature is not achieved when using a Class 5 CI and the BI reading is positive indicating a sterilization failure, the Class 5 CI will also indicate a sterilization failure.

Internal chemical indicator: A Class 3, 4, 5, or 6 type of CI that is placed inside a HDO-assembled package that is used to verify the package was exposed to the physical sterilization conditions.

Multi-variable indicator: Class 4 CI that are designed to react to two or more of the critical variables of the sterilization cycle.

Physical monitors: The gauges or displays on the sterilization machine that indicate pressure, temperature, and time which are recorded on a record chart or computer print-out for each load.

Process challenge device (PCD): Term that replaces old terms “challenge pack” or “test pack”; refers to the use of BIs and the Bowie-Dick air removal test pack.

Process indicator: General term that refers to BIs and CIs.

Process monitoring devices: General term that refers to all types of sterilization monitoring devices including BIs and all classes of CIs.

Single-variable indicator: Class 3 CI that is designed to show the exposure to one sterilization process, e.g., single variable is temperature.

Steam sterilization: Sterilization process that uses steam as the sterilizing agent to kill microorganisms.

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