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# A Guide to Sterility Assurance

Practical Concepts For Your Institution


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## Contents

## Overview

*A Guide to Sterility Assurance* is a practical handbook for healthcare workers who are responsible for an organization's decontamination and sterilization processes. The Guide presents a comprehensive quality control program for handling contaminated medical devices and equipment, and processing them with appropriate checks and monitors to provide optimum conditions for sterility.

Steam and ethylene oxide sterilization are discussed as well as packaging, labeling, and the different kinds of monitors, biological and chemical indicators. Sample flow charts for identifying step by step procedures, and forms for recording quality control data are provided so that central processing services can adopt these tools as appropriate.

## Objectives

Upon completion of this Guide, the healthcare worker should be able to:

1. Discuss the purpose of developing a sterility assurance and quality control program.

2. List the recommended steps in the transportation, decontamination, sterilization, inspection, packaging, and labeling of medical devices and equipment.

3. Explain how to select cycles for steam and ethylene oxide sterilizers.

4. Identify the application of various sterilization process controls including mechanical, chemical, and biologic monitors.

5. Develop sterility assurance flow charts and quality control forms for your work setting based on the examples provided.

## Introduction To Sterility Assurance

A fundamental value for healthcare workers today is providing safe working conditions and equipment in the patient care process and protecting themselves and others from exposure to pathogens. This requires that the healthcare worker be knowledgeable about OSHA regulations and safe practices for their setting. It also requires exquisite attention to all phases of quality control.

Quality control processes standardize the activities and steps necessary to produce a consistently sterile product and safe, optimum functioning instruments and equipment. Sterility assurance is a level of confidence that each product will meet the predetermined standards. The person using the product is assured or is confident that the product is sterile (i.e., free from all forms of microbial life), free of harmful residues, and if applicable, nonpyrogenic. This is the standard of quality that each patient should receive. Sterility assurance is more inclusive than just monitoring the sterilization process. It encompasses all of the activities that healthcare workers do that are necessary to produce a sterile device.

There is no feasible way to directly determine that a particular item is sterile prior to use. We rely on secondary or indirect means to verify sterility. The more variables we can control, the greater the probability that the system will produce a sterile device. A comprehensive system (i.e., several points of measurement) provides a higher level of confidence than a single point system. A sequence of repeatable conditions that have been proven to effectively promote device sterilization must be implemented in all phases of the sterilization process, from handling and containment at point of use to sterile storage. When there is verification and documentation that all the physical parameters of the processing system have been consistently met, then processed devices may be released for use with a high level of confidence that they are sterile. Sterility assurance or quality control is ongoing testing, monitoring, and calibration of instruments and equipment prior to use in the delivery of patient care. It also requires that evaluation of information in a manner that can be acted upon to attain the highest probability that devices are safe for patient use.

## In This Book: A Program for Sterility Assurance

A method of assuring sterility is a critical element of the processing activity. Controls and monitors must be built into the system to assure the user that the processed device will be acceptable and consistent in quality. Processing activities should be performed correctly each time. This can be done by developing specific detailed procedures, giving employees education, training, and pragmatic tools for them to know if the task was completed correctly. This method of quality control should be built into every task of the processing system. It is the foundation of any quality control program.

This sterility assurance program model is presented as a guide that may be used by any service in a healthcare organization where devices and equipment must be decontaminated and sterilized. It can be modified or condensed to fit particular processing situations. The purpose of the model is to demonstrate the interrelationships among all phases of the process. All monitoring controls, methods, and examples used in this sterility assurance model are in alignment with nationally accepted standards and recommendations.

The first step in developing a sterility assurance program is to list each step in the process, beginning at point of use and ending in sterile storage. (See the flowchart "A Typical Sterility Assurance Process" in the Appendix.) Next, procedures must be collaboratively developed that define the expected outcome in measurable or quantifiable terms for each step of the process. Once the procedures have been developed, they should be reviewed by the central processing department, the user department, and the infection control practitioners, to ensure they will achieve the outcome in an effective and efficient manner. It must be recognized that the necessary resources, including time for program development and educational preparation of all employees, must be allocated if the system is to succeed.

Finally, control checkpoints are assigned. Sterility must be assured at a reasonable cost. Control checks (CC) need to be selected where they will do the most good at the least cost. (See the flowchart "A Typical Sterility Assurance Process with Control Checks" in the Appendix.) Each point requires an assessment as to whether the desired result was obtained. These assessments are designed to cover an observable or measurable outcome. The sample size and frequency should be determined by the infection control committee.

Sample forms for suggested control checks are provided for each step in this Sterility Assurance program. In addition, this program provides a series of six flowcharts that facilitate classroom instruction and in-service activities. These flowcharts can also be reproduced as posters for on-site reinforcement of your Sterility Assurance procedures.

## AMSCO: A Leading Resource

Over 100 years of leadership in sterilizer technology has positioned AMSCO as a leading resource in the techniques of sterility assurance. This *Guide to Sterility Assurance* is intended to provide you with a benefit of that experience—to impart the knowledge we've gained in working with the needs of tens of thousands of customers, as well as working to perfect our own equipment. We hope you will find this Guide useful. Please feel free to contact us with any questions and problems in developing and maintaining the Sterility Assurance program that's right for your institution. You can reach your AMSCO representative at (800) 846-2727.

## Instructions to Receive Continuing Education Credit

This is a self-paced independent continuing education activity. The nurse or central processing healthcare worker may choose to complete this course in one sitting or during a few concentrated efforts. Since the unit is relatively short and can be completed in a couple of hours, it is suggested that learners complete the unit in one or two sittings.

To use this unit of instruction in an optimal manner, learners should complete activities in the following sequence:

1. Read the unit objectives and determine whether this subject is pertinent and useful to your professional setting.
2. Review the test questions to further assist you in focusing in on key areas and terminology.
3. Study the content of the Guide.
4. Answer the self-assessment test questions.
5. Evaluate your performance using the answer key.
6. Follow the steps under "Continuing Education Credit" to receive formal credit for completing this unit.

## Nurses Accreditation/ Credit Hours

This offering for **2** contact hours is sponsored by **Education Design**, which is accredited by the American Nurses Credentialing Center Commission on Accreditation (ANCC). Courses sponsored by an ANCC accredited agency will meet relicensure requirements in the following mandatory states; Colorado, Kentucky, Massachusetts, New Hampshire, New Mexico, Ohio, and Texas. In addition, Education Design is a State Board approved provider of Nursing CE in the following states:

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   Any questions, please call 1-303-692-9758.

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## Central Service Professional Accreditation

Approved by the NICHSPDP for 2.0 contact hours when entire booklet is completed along with flow charts. Individuals certified through the NICHSPDP are not required to submit the $10 fee or form to any agency. CEU credit will be given upon successful completion of this self-study program (including passing of post-test). Certificates of completion should be provided by the Department Head indicating the Title of the Program, date provided and Department Head's signature.

## About the Author

Marimargaret Reichert, RN, MA, well-known author and lecturer, has over 25 years' experience in the healthcare field including 17 years in clinical management. She has worked in hospitals ranging from 50 to 2500 beds, holding such positions as head nurse, Division Head of Vascular Services, Staff Development Coordinator and Clinical Nurse Coordinator in Perioperative Nursing, and Director of Central Sterile Reprocessing. Ms. Reichert is recognized for her innovative approach in the development of management and organizational systems that improve the quality of patient care while increasing revenue or reducing operating costs. Throughout her career, she has promoted new technology with a focus on its implementation in an economically responsible manner. She has been involved with the Sterilization Standards Committee of the Association for the Advancement of Medical Instrumentation (AAMI) since 1980, and holds memberships in the Association of Operating Room Nurses (AORN), Association of Practitioners in Infection Control (APIC), American Society of Healthcare Central Service Personnel (ASHCSP), the Society of Gastroenterology Nurses and Associates (SGNA), and the International Association of Healthcare Central Service Material Management (IAHCSMM).

## About the Photography

Our thanks to the staff of St. Vincent Hospital, Indianapolis, IN, for making their facilities available to our photographer. Busy schedule notwithstanding, they provided the materials and locations that enabled us to bring this Sterility Assurance Guide to completion.

## Handling and Containment at Point of Use

Producing a sterile medical device is a complex process that is dependent upon the successful completion of all the steps from the time of use until the time for the next use. Procedures must be established to meet the criteria for effective processing as well as the requirements for employee safety as stated in the 1991 Occupational Safety and Health Administration (OSHA), Occupational Exposure to Bloodborne Pathogens; Final Rule, and all other OSHA safety requirements.

In the operating room, gross soil and debris are wiped from the surgical instruments throughout the procedure. In other areas, the person preparing the device for return to the processing area will remove the gross soil and debris with a sponge moistened with water. Disposable sharps such as disposable knife blades and needles must be removed at point of use and discarded in a puncture- and leak-proof container. Reusable textiles are removed and placed in the appropriate container.

Contaminated supplies are contained for transportation to the decontamination area in a manner that will protect personnel and the environment without damaging the items. The cart must be identified as "Biohazard" when it contains contaminated supplies. This can be accomplished by covering a cart with a "Biohazard"-labeled plastic cover, or by using a closed cart with a label holder containing a "Biohazard" label. Some methods of containment include placing prepared items that do not pose any risk of puncture (e.g., a manual resuscitator) into a plastic bag, placing a tray of surgical instruments into a rigid sterilization container system with solid bottoms, or placing the tray of instruments into a puncture- and leak-resistant covered container designed expressly for containment of contaminated supplies. The prepared items should then be placed on a cart that has been labeled "Biohazard" for transportation. Containers of solutions must be sealed or secured to prevent spills during transport.

**CC1**

Incorrect handling and containment of contaminated supplies could result in exposure for individuals who will subsequently contact the device. For this reason, the procedure should be audited during and immediately following the preparation for transport, rather than after a problem has occurred.

### Control Check #1 should include the following points:

- Personnel performing this task are wearing appropriate protective attire.
- Appropriate leak-proof, puncture-proof containers are available at point of use.
- Disposable sharps are discarded at point of use.
- Contaminated instruments are contained at point of use.
- Contaminated items are correctly labeled (i.e., BIOHAZARD).
- Contained body fluids (e.g. suction containers) are secured to minimize risk of spills.

A sample form for this control check is available in the Appendix for you to copy and use.

## Transportation

The contaminated supplies should be transported as quickly as possible to the decontamination area. The method of transport should ensure that containment of the contaminants is maintained (e.g., not leaving unlocked soiled casecarts unattended in public access hallways).

**CC2**

## Cleaning and Biocidal Process

As soon as the contaminated supplies arrive in the decontamination area, they should be sorted and prepared for the decontamination process. Devices that are designed to be disassembled should be taken apart. Pretreatment processes such as enzymatic soaks should be completed at this time.

The purpose of the decontamination process is the removal of soil, and the reduction in the number of potentially infectious microorganisms. It is necessary so that the device can be safely handled by personnel in the preparation area who are not wearing protective attire. Potentially infectious, a relative term, is based on such variables as type, number and virulence of organisms on a device, susceptibility of individuals to disease, and the route of transmission (e.g., inhalation, percutaneous or ingestion). There are many different devices constructed of many different materials. For this reason, a single universal decontamination process cannot be recommended. The critical element is to select a process that will minimize the risk to the employee while maintaining good care and handling of the device. (See the flowchart "A Decision Matrix for Selecting an Appropriate Decontamination Process" in the Appendix.) This flowchart illustrates the various options.

## Manual Cleaning

All hospitals clean some specialty and complex instruments manually. In many hospitals, however, manual cleaning is the only method available. While manual cleaning can be a very effective process for the removal of gross soil and debris and reduction of microorganisms, there is less assurance of the efficacy of this process because it cannot be monitored. The actual mechanics of manual cleaning with a brush, if not performed under water, can introduce aerosols into the air. These airborne contaminants have the potential of transmitting some diseases to the employee.

**CC3**

### Control Check #2 should include the following points:

- All contaminated items have remained contained according to the procedure.
- Containers of body fluids have remained secured.
- Transport cart has remained correctly labeled as "biohazardous" during transport.
- Transport cart was attended throughout the transport to processing department if public corridors were used.

### Control Check #3 should include the following points:

- Personnel performing the task are wearing appropriate protective attire.
- Instruments are disassembled correctly according to the procedure.
- Enzymatic pretreatment, if required, is performed correctly.
- Manual cleaning is correctly performed according to the procedure.

Sample forms for these control checks are available in the Appendix for you to copy and use.

## Automatic Cleaning

When possible, items should be automatically cleaned. Automatic processes reduce the risk of employee exposure when compared with the manual process. Items must be prepared properly to optimize the process. Specialty baskets may be provided by the manufacturer of the equipment. Automatic systems can offer a high level of confidence that the outcome was attained because the process can be physically monitored.

### Washers

Washers clean the device with hot water (150° F), cleaning agents and the mechanical action of the jet sprayers. The items are then rinsed with hot water at 180° F and exposed to a drying process at 240° F. Many items that cannot withstand the pressure and/or temperature (270° F) of the washer/sterilizer process can be effectively processed in a washer.

The washing process can be chemically and physically monitored. Chemical indicators (CIs) for the washing process are available. These CIs are designed to sense and record surface temperatures. They are designed as multiple-point (160°, 170°, 180°, 190° F), nonreversible, chemical-change temperature recorders.

Cycle records indicating exposure time and temperature should be reviewed at the completion of each cycle to ensure the preset parameters have been attained, and the data should be filed in a record-keeping system. This information documents the physical parameters (exposure time and temperature); it does not document actual microbial kill.

Routine, periodic review should include a comparison of cycle records. This comparison can provide valuable information about the consistency of machine performance. It may also highlight shifts in operational performance that indicate the need for preventative maintenance work, thereby eliminating some of the emergency service calls due to breakdowns. With the AMSCO Stage 3 control installed, this data is automatically recorded. With the older models, one must look at the gauges to see the temperature.

**Washer/sterilizers**

The washer/sterilizer process can be monitored mechanically, chemically and biologically. The biological indicator (BI) selected must be one that has been designed for a wet process (e.g., the biological indicator must be able to survive the wash cycle before the sterilization cycle). Some biological monitoring systems also contain a chemical indicator. This combination provides more comprehensive information. The response of the CI provides instant information about certain process parameters and, after incubation, the BI provides the assurance of microbial kill.

**CC4**

Immediately after the decontamination process and before the instruments are inspected, the employee should verify that the cycle parameters were attained. This can be accomplished by visual observation of the gauges and documentation during the process or by checking the printout upon completion of the cycle.

**CC5**

## Inspection for Cleanliness

The first step in the preparation process is the inspection for cleanliness. Any device with visible soil, or suspected retained soil in areas that cannot be visually observed, should be returned to the decontamination area for further processing.

## Reassembly

Before a device can be inspected for functionality, it must first be assembled. Step-by-step instructions should be provided by the device manufacturer.

## Inspection for Functionality

Some items require inspection for functionality. It makes little difference if the device is clean if it does not work correctly. When an inspection process is necessary to verify functionality, the device manufacturer should provide the testing protocol. These recommendations should include go/no-go inspection criteria. In some instances, such as textile pack preparation, the hospital may establish, with the guidance of the textile manufacturer, its own criteria for the number and size of patches. In other instances, the hospital may wish to establish additional inspections that it feels are necessary for its situation.

**Control Check #4 should include the following points:**

- Items are correctly placed in the tray or basket.
- The CI is correctly placed in the center of the load.
- The BI is correctly placed.

**Control Check #5 should include the following points:**

- The correct cycle was selected.
- The cycle parameters are correctly documented.
- The end point response of the CI is acceptable.
- The BI is correctly prepared and incubated.

Sample forms for these control checks are available in the Appendix for you to copy and use.

## Preparation

### Steam Sterilization

Preparation of all items to be steam sterilized must facilitate air removal, steam penetration and revaporization. CIs should be placed in the most difficult-to-reach area within the package to provide evidence that one or more of the conditions needed for sterilization actually occurred at that point.

- Textile packs should not exceed the size, weight and density as recommended by the textile manufacturer. For 100% cotton or cotton/polyester blends, the size of the pack should be no greater than 12" x 12" x 20" with a weight of 12 lbs. (or less), and a density of no more than 7.2 lbs./cu.ft. (Illustration 1). The chemical indicator should be placed in the center of the pack between layers of goods, not between stacks of items.
- Basin sets should be prepared so that all basins are placed in the same direction. Graduated nested basins should differ in diameter by at least one inch. Position items so that when placed on the sterilizer cart, they are standing on edge-tilted for drainage. Place absorbent surgical towels between each nested item so that the towel touches the inner surfaces of each basin (Illustration 2).
- Instrument sets should be prepared in wire mesh or perforated-bottom trays. The weight of the instrument set should be based on the design and density of the individual instruments comprising the set, distribution of mass within the set, and the ability of the employee to use good body mechanics in transferring the set to and from the sterilizer cart and to and from storage after sterilization (Illustration 3).

The judicious use of absorbent cotton surgical towels when preparing instrument sets will minimize the occurrence of wet packs caused by inadequate condensate drainage or inadequate revaporization. A towel should be used to line the inner bottom of the instrument tray. Additional towels may be needed between the tray and the wrapper (if wrappers are used rather than rigid containers) and around heavy metal instruments.

**Illustration 1:**
**Textile pack prepared for sterilization.**

**Illustration 2:**
**Basin set prepared for sterilization.**

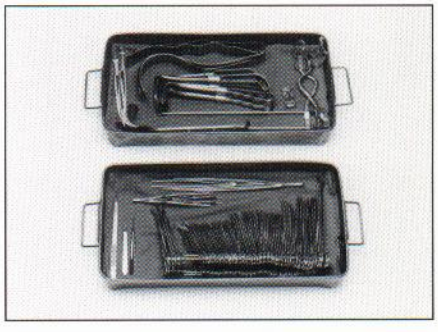

**Illustration 3:**
**Instrument set preparation. Dissection instruments in one basket, retractors in another.**

### Ethylene Oxide (EO) Sterilization

Preparation methods used for items to be sterilized by EO are critical to assuring that all parts of the item have contact with the sterilant, that toxic EO by-products are not formed, and that items can be adequately aerated to remove residual EO after the sterilization process. Chemical indicators should be placed in the most difficult-to-reach area within the package to provide evidence that one or more of the conditions needed for EO sterilization actually occurred at that point.

Preparation must be performed in an area with controlled relative humidity. It is recommended that the relative humidity be maintained within 35% to 70% throughout the processing department (Association for the Advancement of Medical Instrumentation [AAMI] 1992).

Although humidity is essential for sterilization with EO, excessive moisture (i.e., water droplets) forms a barrier to sterilization and facilitates the formation of toxic EO by-products. Guidelines for preparing supplies for EO sterilization include:

- All products and packaging must be preconditioned (e.g., held for a minimum of 2 hours in a controlled environment with a relative humidity of 35% to 70%). Adequate hydration of products makes microorganisms more susceptible to EO.
- Droplets of moisture must be removed before preparing the item for sterilization. The water droplets provide a barrier protecting the microorganisms by inhibiting contact with EO. Excessive moisture increases the probability of formation of ethylene glycol, a liquid which cannot be removed by aeration.
- Items must not be dried by using heated forced air. Although the heated forced air will remove the water droplets, it will also remove the moisture from the material that is essential for sterilization.
- Some devices may require special preconditioning procedures. The manufacturer of every device for which EO sterilization is recommended should be asked if any special preparation techniques are needed.

## Packaging

There are many types of packaging materials acceptable for use in the healthcare facility. These include textile wrappers, nonwoven (disposable) wrappers, rigid container systems, and pouch packaging. The type of packaging material selected will depend on the sterilization method selected, the type or number of devices, and the needs of the end user (e.g.,

whether aseptic presentation is required). For example, an acceptable packaging material for steam would incorporate the following attributes:

- Be able to withstand pressure changes.
- Be able to tolerate moist conditions.
- Be able to tolerate high temperatures.
- Allow the removal of air.
- Allow the penetration of the sterilant.
- Allow drainage of condensate and removal of steam.
- Provide a barrier to microorganisms after processing.

Acceptable packaging materials for EO would incorporate the following attributes:

- Allow the penetration of the sterilant.
- Allow the removal of the sterilant.
- Allow removal of EO during the aeration process.
- Will not react with EO or other chemicals.
- Provide barrier to microorganisms after processing.

## Labeling - Product and Process Identification

Each package should be labeled to identify the contents and process lot control information. Generally, the lot control number should designate:

- the date of sterilization.
- the sterilizer identification number or code.
- the cycle number.
- the operator's initials

CC6

## Placement of Supplies on the Sterilizer Cart

### Steam

Supplies should be placed on the cart in a manner that will allow air removal and contact of steam to all surfaces. General recommendations include:

- Correct orientation of the devices and adequate space between packages (e.g., not crowding too many packages on a shelf or in a basket).
- Items should not touch the walls of the sterilizer. Peel pouches should be placed in the vertical position.

**Control Check #6 should include the following points:**

- Items are prepared correctly as described in the procedure.
- Instrument sets contain the correct type and number of instruments.
- Basin sets have adequate space between each basin and all items are placed in a manner that will allow drainage of condensate and complete drying.
- Multiple-part devices are assembled correctly.
- Devices that require functionality inspections are within specifications.
- Enclosure (contents card or instrument count sheet), if added, is correctly completed.
- Items/instruments are placed in the correct arrangement in the basket or on the tray as described in the procedure.

A sample form for this control check is available in the Appendix for you to copy and use.

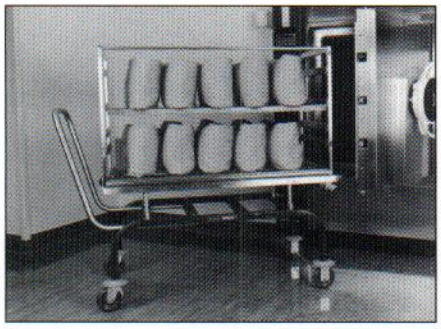

**Illustration 4:**
**Textile packs placed on cart with folds of contents perpendicular to shelf and spaced to allow for removal and steam penetration.**

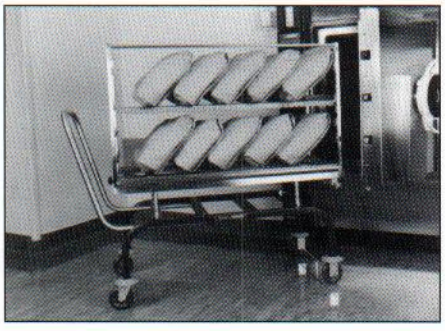

**Illustration 5:**
**Basins placed on cart with all surfaces of the contents of each set positioned to allow removal of air, steam contact, and drainage of condensate. This requires standardization in preparing the sets, since the contents are not visible once wrapped.**

- Like items should be processed together (e.g., either textile packs, instrument sets, or utensil sets). Standardizing the number and placement of products controls some of the process variables. A higher level of assurance is attained when variables are controlled (Illustrations 4, 5, and 6).
- When different items must be processed together, textile packs should always be placed above instrument sets and utensils. This eliminates the potential for condensate from the instruments dripping onto the textile packs (Illustration 7).

**EO**

The load configuration should be established to ensure contact with the sterilant, adequate aeration and employee safety. General recommendations include:

- Items should be placed loosely, well within the confines of the cart, shelf or basket. If the items are to be transferred from a sterilization chamber to a separate aeration chamber, the load should be configured so that it will not be necessary to touch individual packages during the transfer process. Carts and baskets should be made of non-EO absorbent material.
- Items in peel pouch packaging should be placed in a vertical position.
- Items should not touch the chamber walls.

## Cycle Selection

### Steam

Cycle recommendations provided by the sterilizer manufacturer are general purpose or "generic." They are not device-specific. These generic recommendations for general line surgical instruments, textile packs and utensils (i.e., basin sets) are supported by testing that was performed in the 1950s. These test data may not be applicable to the complex medical devices or newer type textile fabrics being processed in today's healthcare setting. For this reason, the device or textile manufacturer is responsible for providing specific sterilization recommendations based on product testing. (See the chart "Typical Steam 'Generic' Recommendations" in the Appendix which summarizes the most commonly used generic cycles.)

Upon completion of the sterilization process, the carts of sterilized items should be removed to a specific area out of the flow of traffic and away from any ventilation ducts for the cool-down period. This may take an hour or more, depending upon conditions in the cool-down area. The items should not be handled until they are no longer warm to the touch. Products could become contaminated if handled while still hot. As an example, if you were to touch these packages just after removal from the sterilizer, the amount of vapor present inside the package might be sufficient to wet the wrapper from inside to outside, and to carry micro-organisms from your hand through the material of the wrapper or pouch. Also, hot metal items could cause injury to the employee.

### EO

Full loads should be processed. The sterilizer controls are preset to inject a certain amount of EO into the chamber to establish a predetermined concentration of EO. Therefore, the same amount of EO will be injected into the chamber regardless of the size of the load. Full loads are more cost-effective. They reduce the opportunities for operator exposure to EO and result in fewer cycles and, therefore, less environmental release of EO and any diluent gases.

Cycle recommendations for EO sterilization provided by the sterilizer manufacturer are general purpose or generic cycles and are not product-specific. Because of the vast array of products sterilized with EO, the sterilizer manufacturer qualifies the sterilizer by performing simulated load testing using test packs described by AAMI, rather than real products. The sterilizer manufacturer demonstrates,

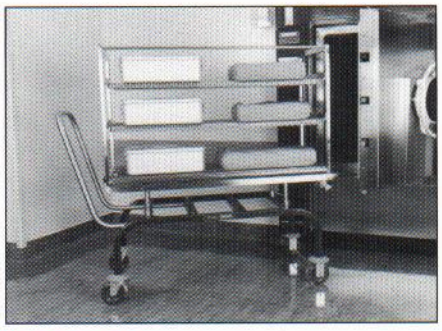

**Illustration 6:**
**Instrument sets (wrapped and containerized) with bottom of tray horizontal to shelf and heaviest sets on the bottom.**

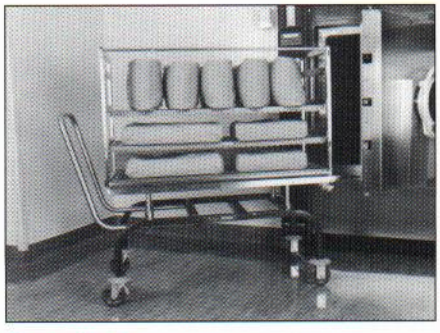

**Illustration 7:**
**Mixed load with metal goods beneath other items and each item positioned as appropriate to its contents.**

to the satisfaction of the Federal Drug Administration (FDA), that the cycle(s) available on any given sterilizer are capable of producing at least a $10^{-6}$ (one in one million) probability of a nonsterile item. In addition, a safety factor is added to the cycle time to allow for some anticipated difference in loads. These cycle parameters may not, however, be adequate to sterilize some devices, depending on design, materials and methods of construction. For this reason, the device manufacturer is responsible for providing specific sterilization recommendations for their device based on product testing. (See the chart "Typical EO 'Generic' Recommendations" which summarizes the most commonly used generic cycles.)

Items that are sterilized with EO must be aerated to remove the toxic residual EO. Because of the many variables associated with the materials and the construction of the device, appropriate aeration recommendations supported by product testing should be provided by the device manufacturer.

CC7

## Sterilization Process Controls

The goal of the sterilization process is the complete destruction of all forms of microbial life on each item being processed. Because microorganisms cannot be seen by the naked eye, the only way to ascertain that the item is sterile is to test it. Because this is not practical, we must rely on secondary or indirect means to verify this outcome. These indirect methods of measurement include mechanical indicators (e.g., gauges, dials and printouts), air leak tests for prevacuum methods, and chemical and biological process monitors. Comprehensive quality assurance for sterilization includes the collection of data from all of these methods to indirectly verify each product is sterile.

### Mechanical Monitors

Mechanical control monitors include time, temperature, and pressure recording devices and gauges. It is important to ensure that the sterilizer is operating correctly and the conditions within the sterilizing chamber meet the required parameters for sterilization. All of the essential conditions necessary for steam sterilization are measured by these mechanical monitors. However, each is measured at just one point in the chamber.

A sample form for this control check is available in the Appendix for you to copy and use.

**Control Check #7 should include the following points:**

- Correct exposure time and temperature are selected.
- Biological Test Pack is correctly placed in sterilizer.
- Documentation is correctly entered into logbook.
- Supplies are correctly placed in basket, on cart, or on shelf.

The mechanical controls for EO sterilization directly monitor only two of the required four parameters (time and temperature). Gas concentration and relative humidity are controlled by the machine, with no practical means available for monitoring. Thus, other quality control measures take on additional importance.

Additional methods of monitoring are recommended to increase the level of assurance by verifying that sterilization conditions have been achieved at multiple points within the load.

### Chemical Indicators

Chemical indicators (CIs) provide information about certain conditions within the package, but do not assure the sterility of the product. CIs are excellent tools for indirectly monitoring one or more parameters of sterilization to provide pass/fail information to the end user. AAMI (1988) provides guidelines for the selection of CIs for steam sterilization.

There are many different types of CIs that will respond to one or more of the parameters necessary for sterilization by steam (time, temperature, steam saturation) or EO (i.e., time, temperature, relative humidity, and EO gas concentration). Before a product selection is made, the processing manager should know what the CI is measuring, and more important, what it is not.

The CI should be placed in an area within the package that would be the most difficult for the sterilant to reach. Illustrations 8, 9, 10, 11, and 12 are examples of CI placement in supplies being processed with steam.

Each CI should be examined by the individual opening the package and an assessment should be made as to the acceptability of the CI response. If a CI within a package does not reach an acceptable end point response, the product should not be used. This information should be given to the manager of the processing department for further investigation. The unacceptable end point response of the CI could signal items have been incorrectly packaged or loaded, or it could be identifying an equipment malfunction which would affect the sterility of all products processed in that load. The manager of the processing department should first consider the content of the particular package and the ease or difficulty of its sterilization. In an existing quality system process, parameter recordings from the machine would already have been found to be acceptable or the load would not have been released. But

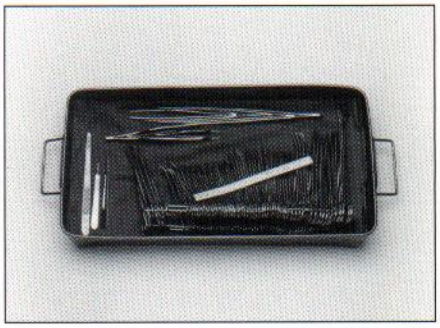

**Illustration 8:**
**Placement of CI in an instrument set that will be wrapped.**

**Illustration 9:**
**Placement of CI in an instrument set that will be containerized.**

**Illustration 10:**
**Placement of CI in a basin set.**

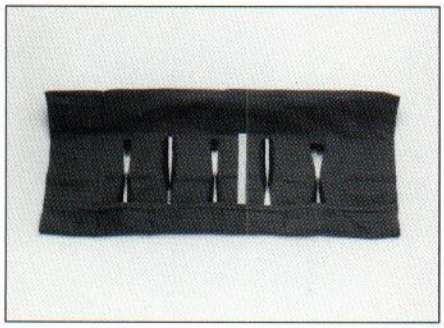

**Illustration 11:**
**Placement of CI in a specialty instrument set such as osteotomes.**

**Illustration 12:**
**CI should be placed in the center of the textile pack between the layers.**

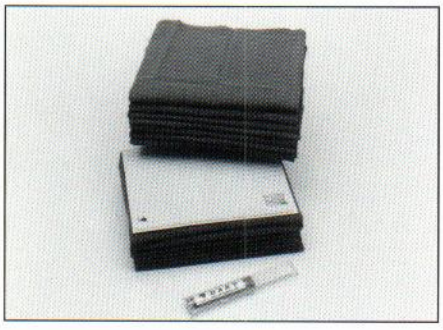

**Illustration 13:**
**In-hospital prepared test pack with a daily CI sheet and commercially prepared test pack.**

these parameters are monitored at a single point and may not indicate the conditions throughout the load.

If similar packages to the one in question from the same load are still available, several should be opened and the CI examined. Multiple failures from the same load may prompt a decision to recall some or all items from that load, depending on whether the fault is thought to be a packaging/loading error, an equipment failure, or of unknown cause. (See "Chemical Indicators: A Problem-solving Flowchart" in the Appendix.)

### Bowie-Dick Test

The Bowie-Dick test is a diagnostic test used to validate the effectiveness of the mechanical air removal system for prevacuum steam sterilizers. Sterilizing conditions will not be attained if air remains in the chamber. This test should be completed daily.

The Bowie-Dick test pack may be prepared in the department following the guidelines provided by AAMI (1992). Commercially prepared test packs are available and widely accepted. (Illustration 13.) They offer the advantages of convenience and consistency over in-hospital prepared test packs. It is recommended that the manufacturer of the test pack provide scientific data that supports the equivalency of their test pack to the AAMI Bowie-Dick Test Pack.

The Bowie-Dick test pack is placed horizontally on the lower shelf of the sterilizer over the drain in an otherwise empty chamber. If the sterilizer is used continuously, the test may be completed at any time during the 24-hour period. Many departments that are operational 24 hours a day perform the Bowie-Dick test just after 12:00 midnight. If the sterilizer is turned off, or if the sterilizer is not used during the evening and/or night shift, a shortened cycle (i.e., without the drying phase) should be initiated to properly heat the sterilizer before the test load is initiated. (See "The Bowie-Dick Test: A Problem-solving Flowchart" in the Appendix.)

### Biological Monitoring

A biological process indicator (BI) is a unit containing microorganisms of known concentration and resistance to a given sterilizing agent which can be expected to follow a predictable death rate when exposed to certain parameters. The BI represents a challenge to the sterilization process, and provides the highest level of assurance that microorganisms on the items have been killed. The BI only demonstrates that the conditions

necessary for sterilization have been achieved. It does not indicate that an individual product is sterile. The biological test pack has been designed to present a standardized challenge to the sterilization process. One or more biological process indicators are placed within the center of the pack (Illustration 14). (See "Biological Indicators: A Problem-solving Flowchart" in the Appendix.)

### Steam

For steam sterilization, there are two alternative test packs in common usage today: homogenous hospital-prepared test packs (AAMI 1992) and commercially prepared test packs (Illustration 15). Commercially prepared packs vary greatly in design and contents. They offer advantages of convenience and consistency over in-hospital prepared packs. They generally take up less chamber volume, thus allowing more actual space for patient care products. The manufacturer of the commercially prepared test pack should provide scientific data showing the pack's equivalence to either of two packs as described in AAMI (1992): a homogenous pack or an older heterogeneous pack which was prepared with materials that are no longer available in North American markets. The steam sterilization process should be tested with the BI test pack at least daily and for any load which contains an implantable device. The BI test pack is placed flat in the area of the chamber that is least favorable to sterilization. This area, the "cold point," varies with the sterilizer design, but is normally in the front, bottom section of the sterilizer, over the chamber drain.

### EO

There are two types of in-hospital prepared test packs used for EO sterilizers: a challenge test pack which creates a simulated challenge for EO sterilization, and a routine test pack (Illustration 16) which offers less resistance to the sterilization process than the challenge pack, but more closely simulates actual product configurations being routinely sterilized by EO. The biological test pack(s) is placed in a location(s) within the chamber which is most difficult to sterilize. For example, stratification of the sterilant or variation in the temperature throughout the chamber may inhibit sterilization. In general, the test pack should be placed in the center of the load unless the sterilizer manufacturer indicates that another location is preferred. Commercially available test packs are also acceptable, providing the manufacturer of the test pack can

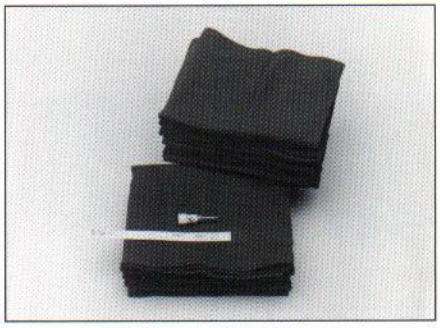

**Illustration 14:**
**Placement of BI and CI in a hospital prepared challenge test pack.**

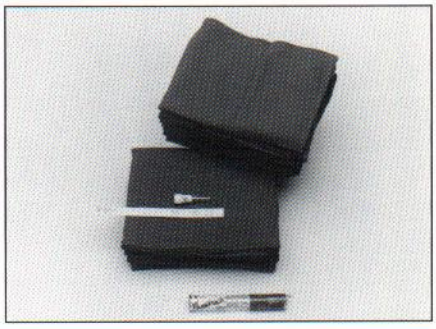

**Illustration 15:**
**In-hospital prepared challenge test pack and a commercially prepared BI test pack.**

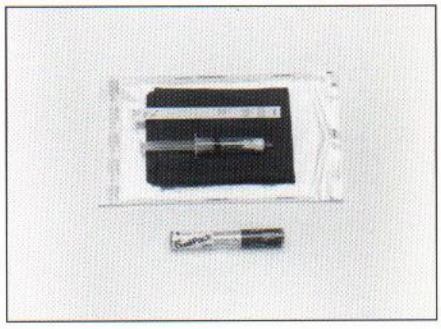

**Illustration 16:**
**In-hospital prepared routine test pack and a commercially prepared BI test pack.**

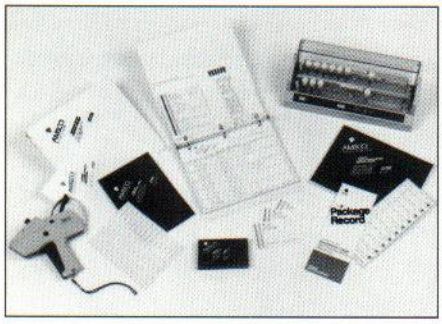


**Illustration 17:**
**Complete sterility assurance record keeping system to insure proper storage and retrieval of data.**

demonstrate equivalence to either the challenge pack or the routine monitoring pack. The biological test pack should be retrieved after aeration. The EO sterilization process should be tested with a BI test pack every load.

"Biological Indicators: A Problem-solving Flowchart" illustrates a decision flowchart in the event the BI test results are unacceptable. (See the Appendix.)

### Product Testing

Routine biological test packs have been designed to create a known challenge to the sterilization process. But the packaging methods and/or loading practices being performed within each facility may be presenting a different and possibly greater challenge to the sterilization process. For this reason AAMI (1990, 1992) recommends periodic verification using CIs and BIs in routinely prepared products.

CIs and BIs are to be placed at different places in the package at the points that would be the most difficult to sterilize (i.e., those most resistant to sterilant penetration). The packaged product is then identified and placed among other products in a routine sterilization load. At the completion of the process, the sample packs are opened, the CIs inspected for end-point reaction, and the BIs prepared and incubated. If acceptable results are attained, there is a greater level of assurance that the packaging and loading practices did not inhibit sterilization.

Verifying that the product can be packaged and loaded correctly before the product is introduced into the institution offers the greatest level of assurance. Testing should include chemical and biological indicator testing, and for steam sterilization, an evaluation of the poststerilization moisture content (i.e., wet packs). Once acceptable results have been achieved, a procedure should be written that contains the specific measurable criteria for the packaging and loading of that product. This practice minimizes work practice variation and offers a higher level of assurance that the results seen during initial evaluation will be repeated.

## Documentation

Documentation establishes accountability. A system should be established that will: 1) collect the needed information; 2) be easy to understand; 3) minimize the potential for error; 4) minimize the volume of paper to be stored; 5) consolidate information whenever possible; and 6) be easy to retrieve.

The sterilization activity records (Illustration 17) for each cycle should include:

- The assigned lot number.
- The contents of the lot or load.
- The exposure time and temperature (if not provided on the sterilizer recording chart or printout).
- The name or initials of the sterilizer operator.
- The results of biological testing.
- The results of the daily air removal test (for prevacuum sterilizers only).
- Reports of nonresponsive or failed chemical indicators from this load found within a package at time of use.

**CC8**

Dust covers, if used, should be applied immediately after cool-down has been completed. All supplies can be placed in sterile storage until needed. Sterility is related to events, not time. Sterile storage should be designed to minimize the events that could contaminate the supplies. Adequate space is needed around sterile materials to allow for air circulation in the room, prevent contamination during cleaning of floors, and prevent contact between sterile items and condensation that may form on interior surfaces of outside walls.

**CC9**

## Conclusion

Attention to the processes and controls involved in the decontamination and sterilization of medical devices and equipment is critical. Protection of self, others, and patients from unnecessary exposure to pathogens and unsafe situations is realistic when an adequate quality control program is developed and implemented.

The costs of the resources (i.e., adequate staff, additional inventory, educational preparation and appropriate equipment) can be justified. The hidden costs associated with product defects include: unnecessary inventory, instrument sets that contain too many instruments, extended procedure time due to instruments or equipment not working, procedures being delayed or canceled, and perhaps overtime pay if the workday is extended to complete the schedule. While these costs are absorbed by the user department, opportunities to lower costs will force managers to scrutinize their operations. Potential savings for the program include reduced processing costs, reduced labor for both the processing and the user departments, and reduced repair and replacement costs.

There is a direct correlation between the allocation of appropriate resources and the ability to produce the product correctly 100% of the time. As the resources are reduced (e.g., inadequate staff, no time for educational preparation, inadequate levels of inventory) the rate of errors, liability and associated costs increase.

Monitoring and evaluating are the dynamic activities that improve the process. Assuring sterility is a critical element of processing activities. A well designed system will ensure that the outcome or product is acceptable and consistent for use in patient care. The professional responsible for the processing activities will be managing and working in a proactive, problem-avoidance system.

**Control Check #8 should include the following points:**

- Cycle time and temperature are verified on graph/printout.
- BI Test Pack was correctly placed.
- Supplies were correctly placed on cart, basket or shelf.
- Supplies were correctly transferred from EO Sterilizer to aerator.
- The BI test pack was correctly retrieved, prepared and incubated.
- Supplies were allowed to cool-down after removal from steam sterilizer.
- Cool-down conditions (e.g., away from traffic, no touching) were controlled and maintained.

**Control Check #9 should include the following points:**

- Sterile supplies are stored at least 8 to 10 inches from the floor, at least 18 inches from the ceiling and at least 2 inches from the outside wall.
- Sterile supplies are positioned so that the packaging is not crushed, bent, compressed or punctured.
- Sterile supplies are stored on shelves that are clean and dry. Sterile storage should be located in a dry area away from any moisture to prevent packaging from becoming moist or wet.
- Sterile supplies that are critical but seldom used are stored in closed cabinets, if possible.

Sample forms for these control checks are available in the Appendix for you to copy and use.

## Resources


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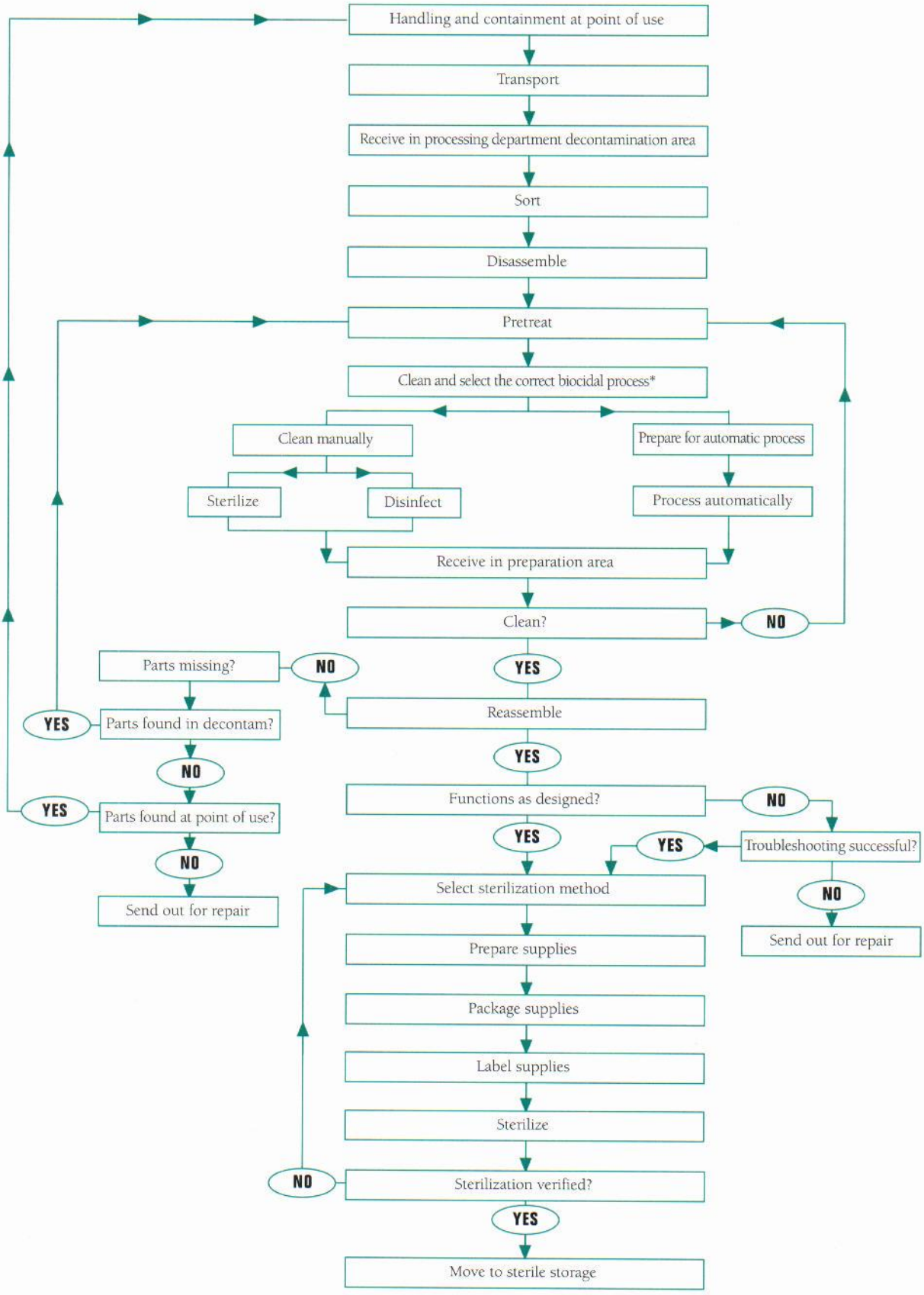
## INSTRUCTIONAL FLOW CHARTS

This section provides instructional flow charts which can be reproduced for use in classroom instruction, in-service activities, and as posters for on-site reinforcement of your Sterility Assurance procedures.

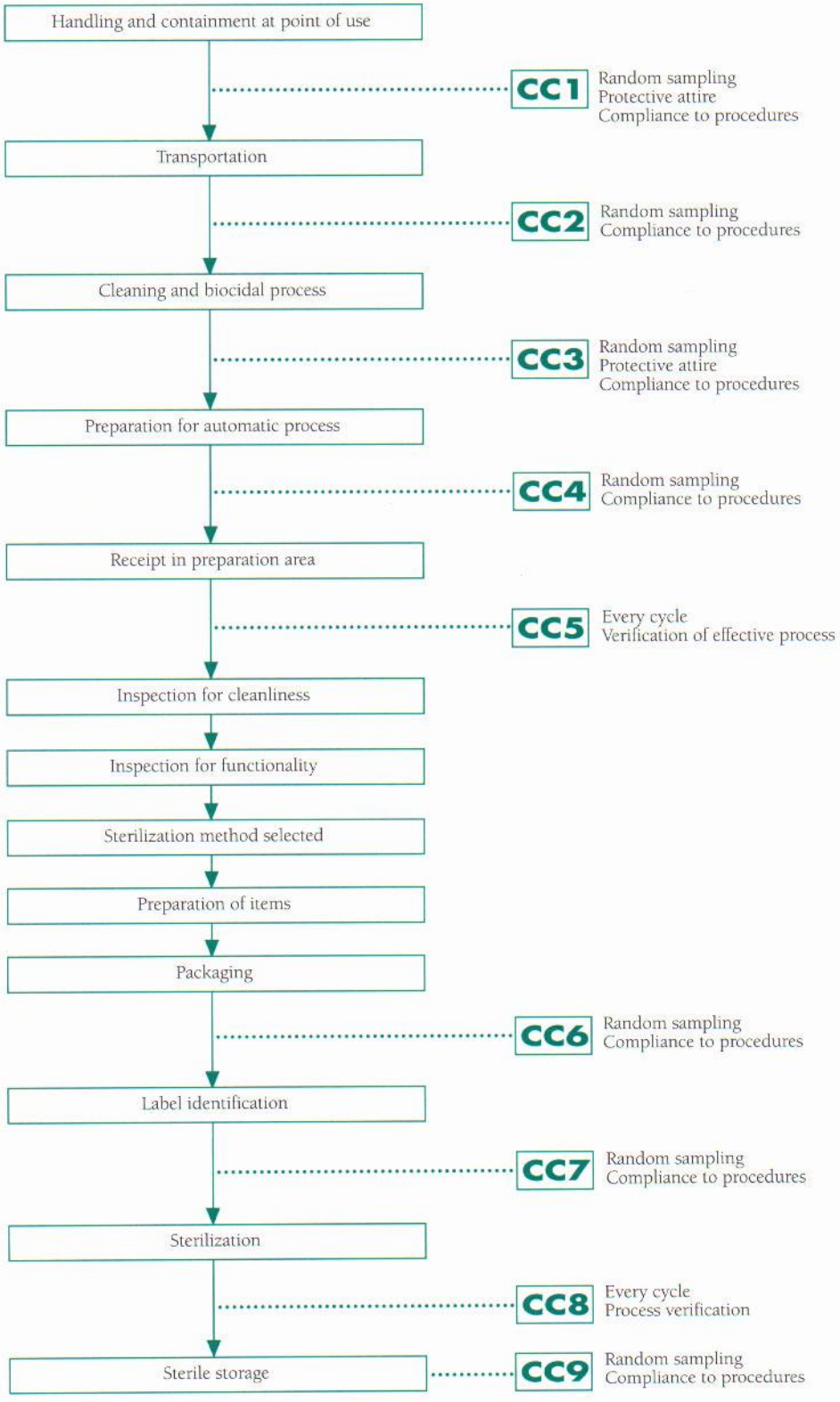
## Contents

## A Typical Sterility Assurance Process

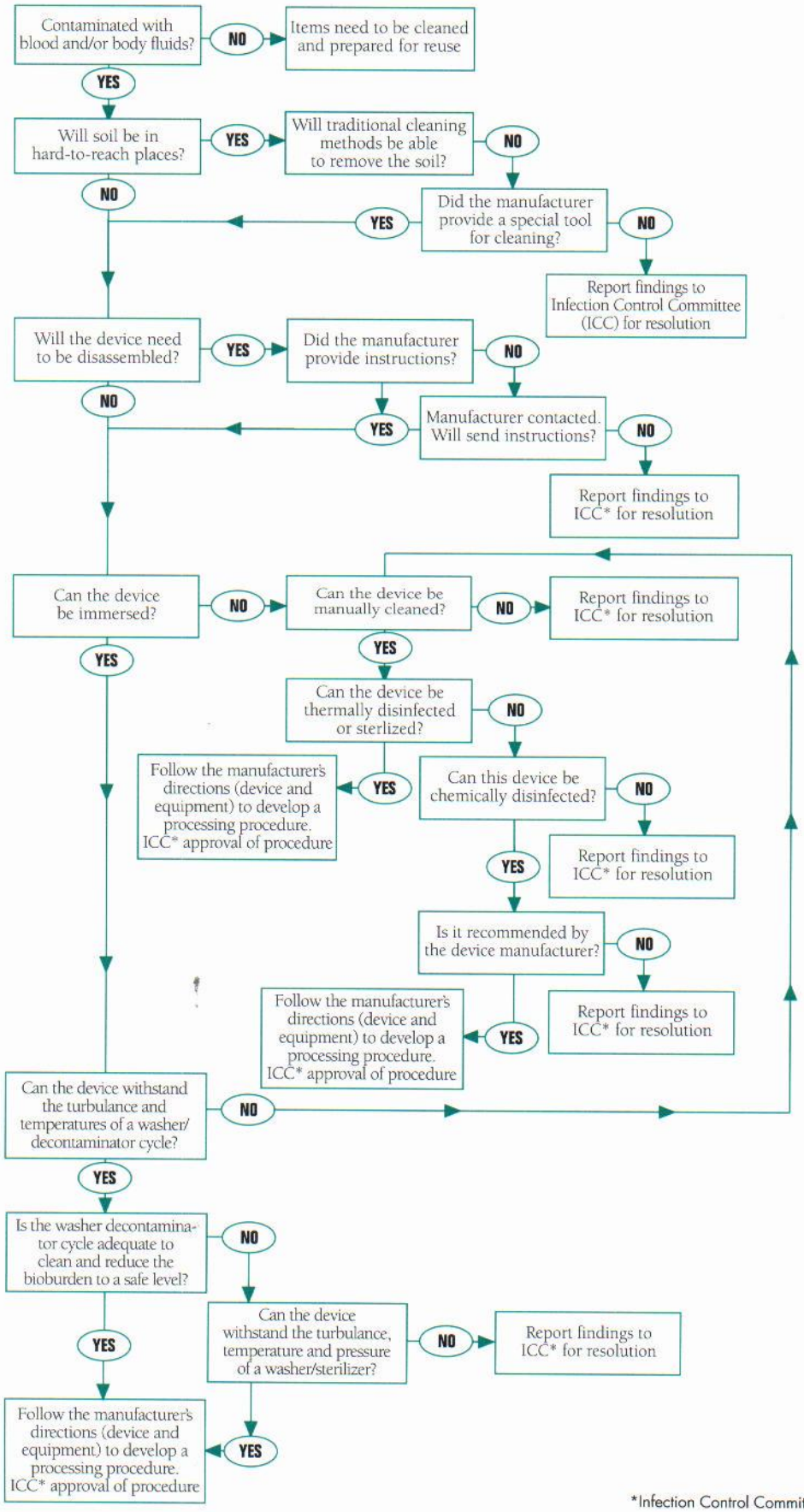



*(See the "Decision Matrix" for selecting an appropriate Decontamination Process)

## A Typical Sterility Assurance Process With Control Checks (CC)



## Decision Matrix for Selecting an Appropriate Decontamination Process




*Infection Control Committee

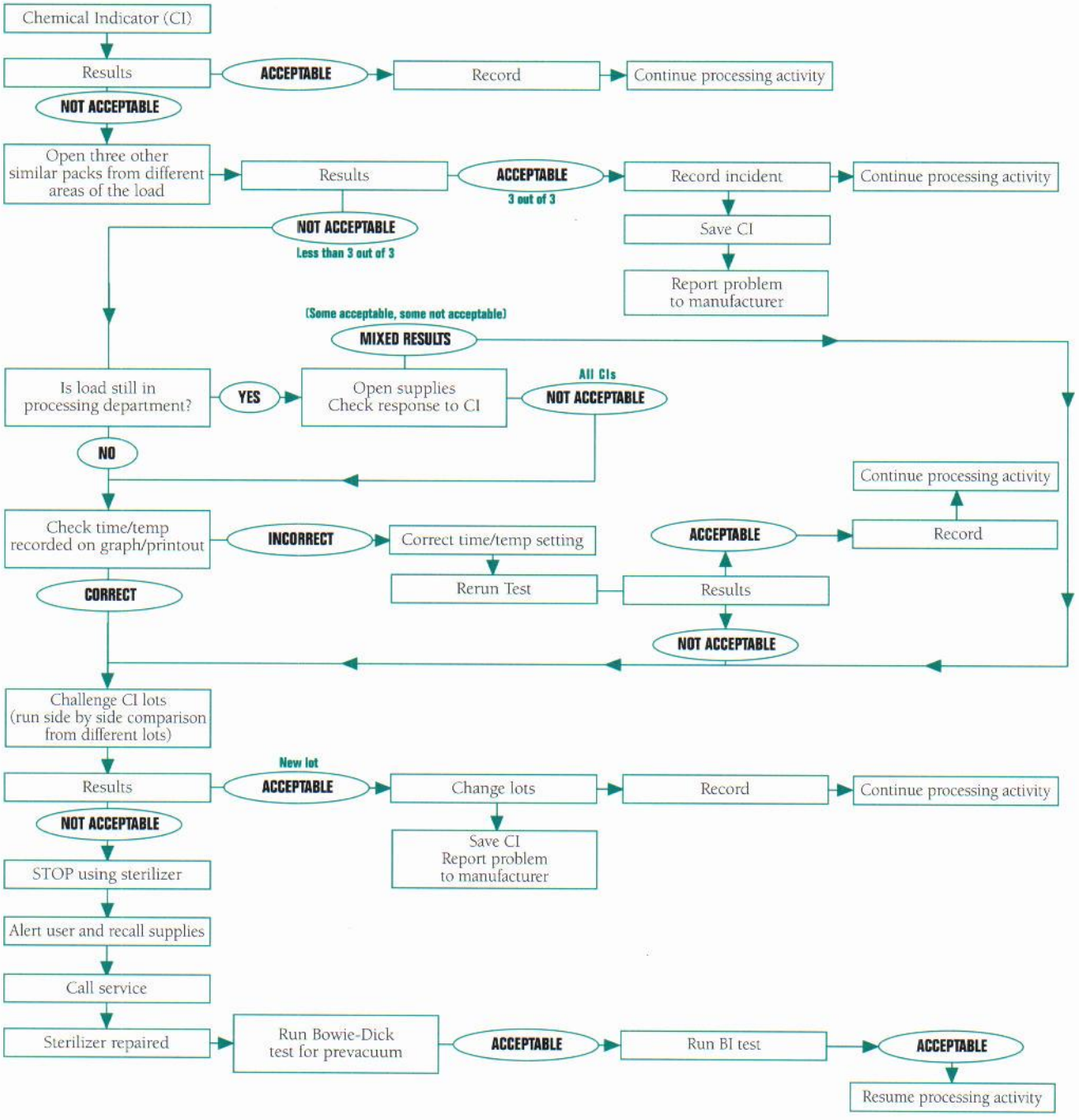
## Typical Steam "Generic" Recommendations

| STERILIZER TYPE | ITEM | TEMPERATURE | ACTUAL CHAMBER TEMPERATURE | EXPOSURE TIME | SELECTED CYCLE DRY TIME |
|---|---|---|---|---|---|
| Gravity Displacement | Instruments, wrapped | 250° F<br>270° F | 252-256° F<br>272-276° F | 30 minutes<br>15 minutes | 30 minutes<br>30 minutes |
| | Linen Packs | 250° F<br>270° F | 252-256° F<br>272-276° F | 30 minutes<br>25 minutes | 15 minutes<br>15 minutes |
| | Utensils | 250° F<br>270° F | 252-256° F<br>272-276° F | 30 minutes<br>15 minutes | 30 minutes<br>30 minutes |
| Prevacuum | Instruments, wrapped | 270° F | 272-276° F | 4 minutes | 20 minutes |
| | Linen Packs | 270° F | 272-276° F | 4 minutes | 5 minutes |
| | Utensils | 270° F | 272-276° F | 4 minutes | 20 minutes |

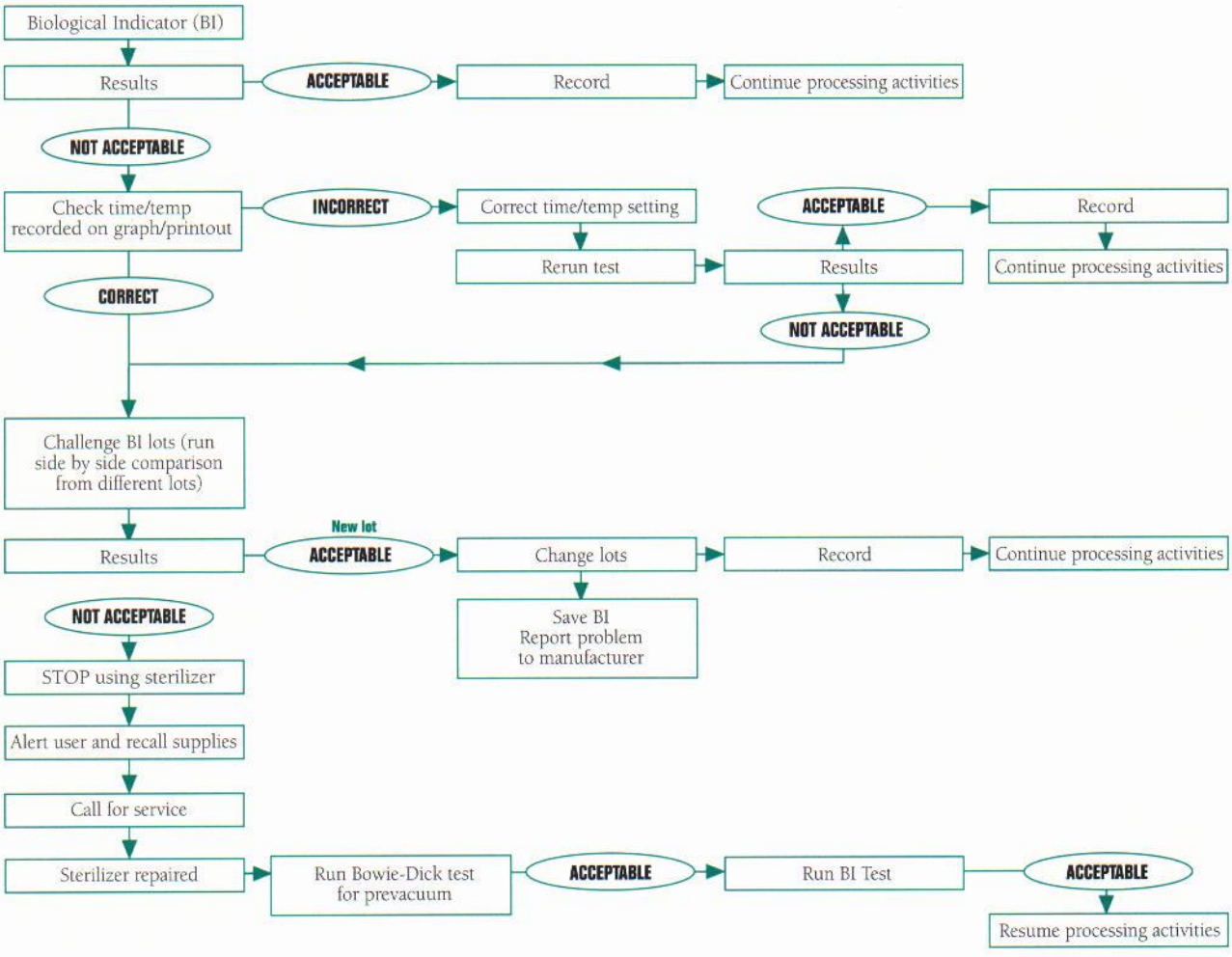
## Typical EO "Generic" Recommendations

| EXPOSURE TIME | EXPOSURE TEMPERATURE | RELATIVE HUMIDITY | CONCENTRATION |
|---|---|---|---|
| 1 hour, 45 minutes | 130° F | 60% | 600 milligrams/L |
| 6 hours | 100° F | 60% | 600 milligrams/L |

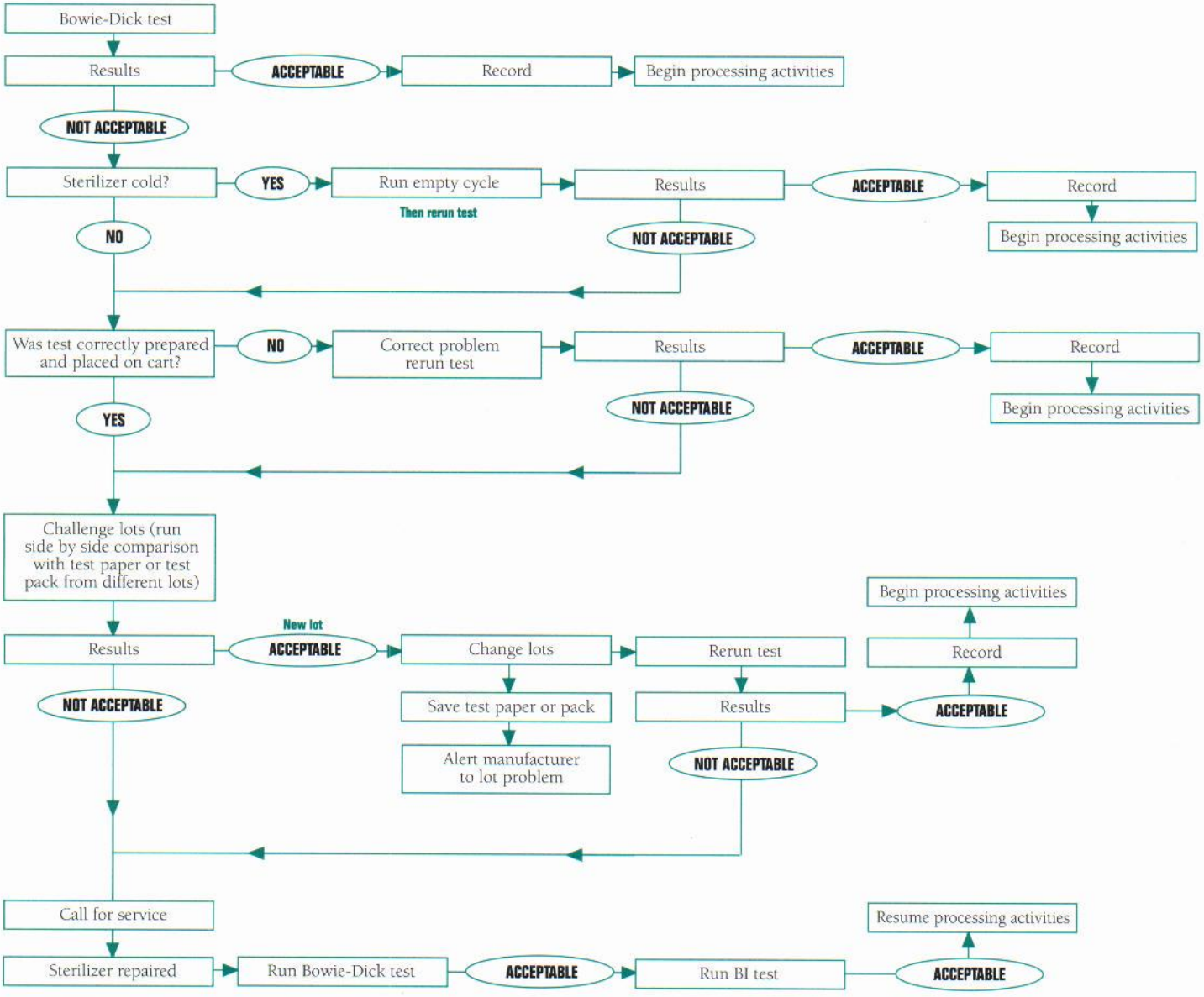
# Chemical Indicators: A Problem-solving Flowchart



## Biological Indicators: A Problem-solving Flowchart



## Bowie-Dick Test: A Problem-solving Flowchart



## CONTROL CHECK SAMPLE FORMS

This section provides sample forms for the control check suggested in this Sterility Assurance program. Copy them and use them in controlling your operation.

### Contents

CONTROL CHECK 1

## Handling and Containment at Point of Use

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Personnel handling contaminated supplies are wearing protective attire as prescribed by OSHA. | | | |
| **2.** Appropriate leak-proof, puncture-proof containers are available at point of use for discarding sharps. | | | |
| **3.** All disposable sharps are discarded at point of use. | | | |
| **4.** Instruments are contained according to departmental procedure. | | | |
| **5.** Contaminated supplies are correctly labeled (i.e., biohazard) | | | |
| **6.** Contained body fluids (e.g., suction canisters) are secured to minimize risk of spills. | | | |

# CC2 CONTROL CHECK 2

## Transportation

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** All contaminated items have remained contained during transport. | | | |
| **2.** Containers of body fluids have remained secured during transport. | | | |
| **3.** Transport cart has remained correctly labeled during transport. | | | |
| **4.** Transport cart was not left unattended at any time during transport to the processing department, if public corridors were used. | | | |

# CC3 CONTROL CHECK 3

## Cleaning and Biocidal Process

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Personnel handling and cleaning contaminated supplies are wearing protective attire as prescribed by OSHA. | | | |
| **2.** Instruments are disassembled correctly. | | | |
| **3.** Enzymatic pretreatment is being performed correctly:<br>• Right product<br>• Right concentration<br>• Right exposure time<br>• Instruments prepared correctly | | | |
| **4.** Manual cleaning is being correctly performed:<br>• Scrubbing under water level with brush<br>• Channels are irrigated<br>• Right detergent<br>• Right concentration<br>• Rinsing correctly | | | |

# CC4 CONTROL CHECK 4

## Preparation for Automatic Cleaning

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Instruments are correctly positioned in the tray or basket. | | | |
| **2.** CI is correctly placed. | | | |
| **3.** BI is correctly placed. | | | |

# CC5 CONTROL CHECK 5

## Verification of the Decontamination Process

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Correct cycle is selected. | | | |
| **2.** Cycle parameters are documented correctly. | | | |
| **3.** The end point response of the CI is acceptable. | | | |
| **4.** The BI is correctly prepared and incubated. | | | |

# CC6 CONTROL CHECK 6

## Verification of Correct Preparation Practices

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Items are prepared as described in the procedure. | | | |
| **2.** Instrument sets contain the correct type and number of instruments. | | | |
| **3.** Basin sets have adequate space between each basin and all items are placed in a manner that will allow drainage of condensate and complete drying. | | | |
| **4.** Multiple-part devices are assembled correctly, if required. | | | |
| **5.** Devices that require functionality inspections are within specifications. | | | |
| **6.** Enclosures (e.g., contents card or instrument count sheet), if added, are correctly completed. | | | |
| **7.** Items/instruments are placed in the correct arrangement in the basket or on the tray as described in the procedure. | | | |

# CC7 CONTROL CHECK 7

## Sterilization Activities

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Correct exposure time and temperature are selected. | | | |
| **2.** BI Test Pack is correctly placed in sterlizer. | | | |
| **3.** Documentation is correctly entered into the logbook. | | | |
| **4.** Supplies are correctly placed in basket, or on cart or shelf. | | | |

# CONTROL CHECK 8

## Verification of the Sterilization Process

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Correct cycle time and temperature are verified on graph or printout. | | | |
| **2.** BI Test Pack(s) was correctly placed in the sterilizer. | | | |
| **3.** Supplies were correctly placed on cart, basket or shelf. | | | |
| **4.** Supplies were correctly transferred from EO sterilizer to aerator. | | | |
| **5.** BI Test Pack(s) was correctly retrieved, prepared and incubated. | | | |
| **6.** Supplies were adequately cooled down after removal from steam sterilizer. | | | |
| **7.** Cool-down conditions were controlled and maintained:<br>• Away From Traffic<br>• NO Touching | | | |

# CC9 CONTROL CHECK 9

## Sterile Storage

Date _____

Procedure _____

Auditor _____

Preparer _____

| | ACCEPTABLE | UNACCEPTABLE | CORRECTIVE ACTION |
|---|---|---|---|
| **1.** Sterile supplies are stored at least:<br>• 8 to 10 inches from the floor.<br>• 18 inches from the ceiling.<br>• 2 inches from any outside wall. | | | |
| **2.** Sterile supplies are positioned so that packaging is not crushed, bent, compressed or punctured. | | | |
| **3.** Sterile supplies are stored on shelves that are clean and dry. | | | |
| **4.** Sterile supplies that are critical but seldom used are stored in closed cabinets if possible. | | | |

## A Guide to Sterility Assurance Self-Assessment

**Instructions: Select the best answer. After completing the assessment, check your responses against the Answer Key. Review appropriate subject areas if necessary.**

1. The purpose of decontamination is:

A. removal of soil
B. reduction in the number of microorganisms
C. prevention of punctures and leaks
D. A and B

2. For steam and ethylene oxide sterilization, where should chemical indicators be placed for optimum performance information?

A. most accessible area within the package
B. most difficult to reach area within the package
C. in the center of the sterilizer
D. in the rear of the sterilizer

3. Excessive moisture or water droplets can interfere with sterilization by ethylene oxide (EO) because:

A. water droplets form a barrier around microorganisms and prevent exposure to EO
B. toxic byproducts are formed that falsely change chemical indicators
C. moisture alters the temperature of the cycle
D. excess water combines with EO and forms another ineffective gas

4. Which of the following is a required characteristic for packaging material for steam sterilization?

A. withstand pressure changes
B. tolerate freezing
C. prevent air circulation
D. non-reaction with EO or other chemicals

5. To select a cycle for either steam or ethylene oxide, what guideline should be followed to achieve sterilization?

A. sterilizer manufacturer
B. product or device manufacturer
C. FDA
D. AAMI

6. Which two parameters are directly monitored by the mechanical control of an EO sterilizer?

A. humidity, gas concentration
B. temperature, gas concentration
C. time, temperature
D. time, humidity

7. Chemical indicators indicate:

A. sterility
B. microbial kill
C. air removal/vacuum
D. cycle conditions

8. AAMI recommends the use of both chemical and biological indicators on a routine basis.

True False

9. A process (procedural and decision making steps) for sterility assurance can be analyzed by use of a form that records acceptable or unacceptable performance and corrective action taken.

True False

10. An appropriate and adequate quality control and sterility assurance program can be both cost effective and provide safety for staff and patients.

True False

## Answer Key

1. D
2. B
3. A
4. A
5. B
6. C
7. D
8. True
9. False
10. True

## Guide to Sterility Assurance
## Evaluation of Continuing Education Activity

**#103446**

Please rate the features of this unit and provide comments.

| | Poor | Fair | Avg. | Good | Exc. |
|---|---|---|---|---|---|
| 1. Effectiveness in meeting the unit objectives. | 1 | 2 | 3 | 4 | 5 |
| 2. Comprehensiveness of subject matter. | 1 | 2 | 3 | 4 | 5 |
| 3. Clarity of presentation. | 1 | 2 | 3 | 4 | 5 |
| 4. Relevance to clinical practice. | 1 | 2 | 3 | 4 | 5 |
| 5. Congruity between the document and test questions. | 1 | 2 | 3 | 4 | 5 |
| 6. Overall quality. | 1 | 2 | 3 | 4 | 5 |

7. Do you plan to change any aspect of your practice as a result of this activity?

Yes _____ No _____

8. What else do you need to learn about this subject?

_____

9. What other topics would you like covered in this format?

_____

10. Other comments?

_____

_____

_____

_____

## Guide to Sterility Assurance
## NURSING REGISTRATION FORM

#103446

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