



Recommended Standards of Practice for the Decontamination of Surgical Instruments

Introduction

The following Recommended Standards of Practice were researched and authored by the AST Education and Professional Standards Committee and have been approved by the AST Board of Directors. They are effective April 16, 2009.

AST developed the Recommended Standards of Practice to support health care facilities in the reinforcement of best practices related to the decontamination of surgical instruments in the perioperative setting. The purpose of the Recommended Standards is to provide an outline that the Certified Surgical Technologist (CST) and Certified First Assistant (CFA) can use to develop and implement policies and procedures for the decontamination of surgical instruments. The Recommended Standards are presented with the understanding that it is the responsibility of the health care facility to develop, approve and establish policies and procedures for cleaning and disinfecting surgical instruments according to established health care facility protocols.

Rationale

The following are Recommended Standards of Practice related to the proper decontamination of surgical instruments (henceforth, simply referred to as instruments) in the perioperative setting. Instruments that are opened on the sterile field, whether used or not used, during the surgical procedure must be thoroughly decontaminated prior to disinfection and/or sterilization. The terms cleaning and decontamination are often used synonymously to indicate a physical and chemical process of removal of organic material, soil and debris, and microorganisms from inanimate objects, such as instruments. The term cleaning frequently, as indicated in the prior sentence, refers to the removal of microorganisms as opposed to killing. However, the Occupational Safety and Health Administration defines decontamination as, “the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.”²⁷ For the remainder of this document, the terms cleaning and decontamination will be used synonymously, and the OSHA definition will apply to both terms, meaning the process removes, inactivates or destroys microorganisms.

When performed properly, cleaning effectively reduces the bioburden in order to prepare the instruments for disinfection and sterilization. The importance of this step cannot be overemphasized since organic material, soil, and debris can block the disinfectant or sterilizing agent from making complete contact with the surface of the instruments. Additionally, cleaning allows for the safe handling of the instruments by health care workers (HCWs).

Standard of Practice I

The cleaning of instruments should begin during the surgical procedure to prevent drying of blood, soil and debris on the surface and within lumens.

1. The CST in the first scrub role should keep the instruments free of debris and blood during the surgical procedure.
 - A. The instruments should be wiped clean using a sterile, water-moistened sponge. Care must be taken that the sponge is not used on the tissues of the patient.
 - B. Instruments with lumens should be flushed with a sterile, water-filled syringe to remove blood and debris and prevent drying of the gross soil.
 - C. Instruments that may not be used for the remainder of procedure, eg, acetabular reamers used during a total hip arthroplasty, may be placed into a basin containing sterile water to soak.
 - D. Saline must not be used, since the chloride ions can cause pitting and deterioration of the finish on the surface of the instruments.

Standard of Practice II

The cleaning of instruments should continue at the point of use post-procedure, including sorting and disassembly of instruments, containment and transportation to the decontamination room.

1. Post-procedure, after removal of the sterile gown and gloves, the CST should wear personal protective equipment (PPE) when breaking down the sterile back table.
2. Instruments should never be soaked in saline or sodium hypochlorite (bleach) solution. The chloride ions in both solutions are highly corrosive, causing the breakdown of the finish on instruments, as well as the metal.
 - A. It is recommended that soaking soiled instruments begin in the O.R. at the completion of the procedure. The instruments can be placed in a basin containing a mixture of sterile water and enzymatic detergent. Refer to the manufacturer's instructions for the correct amounts of sterile water and enzymatic detergent to be mixed.
3. All instruments that were on the sterile field, whether used or not used, are considered contaminated, and a possible source of microorganisms that could cause an infection in HCWs and patients.
 - A. All instruments must be properly separated and placed in leakproof, puncture-resistant containers that are marked with a biohazard label to allow easy identification by other HCWs that the contents are contaminated and therefore hazardous.

- (1) The infection hazard to the surgical team members is greatest during the handling and separation of contaminated instruments at the point of use. However, separation is best done in the O.R.

by the CST who is familiar with the back table set up, including location of the sharps container, as well as other sharps such as trocars in order to prevent injury to other surgical team members.

- (2) A sponge moistened with water should be used to wipe gross soil and blood from the instruments that were used during the surgical procedure. It is recommended not to clean the instruments within a water-filled basin in order to prevent splashing of the fluid on the floor or other surfaces of the O.R.
 - (3) Ringed instruments should be placed in a carrier arranged in single layers or placed on stringers. Box locks should be opened. Assembled instruments should be taken apart. Heavy instruments and delicate instruments, such as microsurgical instruments should be placed in separate trays.
 - (4) Reusable sharp instruments with points or edges should be placed in a separate puncture-resistant, closable container.
 - (5) Instruments should be kept wet in the transport container by covering with a water-soaked towel or spray, foam or gel product specifically intended for this purpose. The instruments should not be transported in the water and enzymatic soaking solution in order to prevent splashing and reduce the weight of the transport container. The enzymatic solution should be properly discarded according to surgery department policy by the CST who is wearing PPE.
- B. Contaminated instruments should be contained during transport from the point of use to the decontamination area.
- (1) Contaminated instruments should be handled as little as possible at the point of use and should be immediately contained and transported to the decontamination area. Immediate containment and transport reduces the risk of surgical personnel's contact with the contaminated instruments.
 - (2) Containment should be achieved through the use of some type of container that has been identified to prevent surgical personnel and other HCWs from contact with the contaminated instruments and prevention of airborne microorganisms during transport. The type of container to be used depends on the items to be transported. Types of recommended containers include closed carts, bins with lids, rigid sterilization container systems, and impermeable bags that can be used alone or in combination.
 - (3) Rigid sterilization container systems with intact, dry filters and closed valves are an accepted method for the transportation of contaminated instruments. However, the use of the container for transportation purposes should be confirmed by consulting the manufacturer's instructions. Some manufacturers recommend not using the same container for transporting contaminated instruments that is also used for the sterilization of the instruments.

- (4) The rigid sterilization container system requires no additional covering, unless the external surfaces have been contaminated with blood and/or body fluids. If the container has been handled and touched by a person who has had contact with blood or body fluids, such as the CST, it should be assumed it is contaminated. In this instance, the container should be enclosed in a red biohazard bag, bin with a lid or closed cart. When purchasing a rigid sterilization container system, the health care facility should consult the manufacturer's information to confirm if the container can be easily and effectively decontaminated.
- (5) The external surfaces of bins with lids, closed carts and other containers should be decontaminated after each use with an Environmental Protection Agency (EPA) - registered, intermediate-level disinfectant. The containers should be thoroughly wiped down externally and internally. The use of a cart wash system is recommended for decontaminating closed carts. Additionally, routine cleaning of the case cart wheels should be performed to remove string and other debris to maintain the easy movement of the wheels.

Standard of Practice III

Cleaning/detergent agents should be selected that will not damage the cleaning equipment and effectively clean instruments.

1. The chemicals in the cleaning agent(s) should not be corrosive to the cleaning equipment including the ultrasonic cleaner, washer-decontaminator, or washer-sterilizer.
2. The chemicals in the cleaning agent(s) should not cause electrolytic action between the instruments and cleaning equipment.
3. The cleaning agent(s) should not be corrosive and damaging to the instruments.
4. Cleaning agent(s) should be easily removed from the instruments by rinsing with water in order to avoid residual chemicals that could corrode and damage the instruments as well as present a danger to the patient.
5. It is recommended to select a detergent with a pH between 7-10 to use in the cleaning of instruments.¹⁶ Detergents that have a pH of higher than 7 are more effective in the removal of organic debris such as blood, fat and feces.¹⁶
6. Antimicrobial solutions, such as iodophors that are used for skin antiseptics, should never be used for cleaning instruments.
7. Manufacturer's instructions for the use of detergents should always be followed. The instructions should be kept on file and accessible at all times by HCWs.
8. The following are the ideal characteristics of a cleaning agent.
 - A. Low sudsing/foaming
 - B. Easily rinsed off
 - C. Disperse organic soil
 - D. Biodegradable
 - E. Nontoxic
 - F. Nonabrasive

- G. Effective on all types of organic soil
- H. Cost-effective
- I. Long shelf life

Standard of Practice IV

Cleaning may be performed manually, mechanically or a combination of both. The selection of the cleaning method should be based upon the type of device and manufacturer's recommendations. However, cleaning alone may not be sufficient to decontaminate items that present a high risk of disease transmission such as surgical instruments and therefore, should undergo a microbicidal process.

1. The manufacturer should provide written instructions for the reprocessing of the instrument(s) or device(s) that include recommendations for the type of cleaning method to be used, type of cleaning equipment and cleaning agent(s).
 - A. The cleaning method should not affect the function of the instruments or devices and should be safe to use by HCWs.
 - B. The manufacturer's instructions should be kept on file and accessible at all times by HCWs.
 - C. Prior to HCWs using cleaning equipment and/or cleaning agents that are not recommended by the manufacturer for particular instruments or devices, the HCW should contact the manufacturer for recommendations, as well as contact the manufacturers of the cleaning equipment and cleaning agent(s).
2. Manual cleaning is recommended for delicate instruments and devices, such as microsurgical instruments, lensed instruments, power equipment, and other instruments that cannot tolerate an automated cleaning process.
 - A. Immersible instruments and devices should be kept submerged in the water to prevent aerosolization. Non-immersible instruments and devices should be cleaned according to the manufacturer's instructions.
 - B. The water with detergent should be kept at a temperature in a range of 27° C to 44° C (80° F – 110° F). Temperatures over 110° F cause coagulation and thus prevent removal of protein substances. Water temperatures that are too cold may not activate the detergent.
 - C. After cleaning, instruments and devices should be thoroughly rinsed to remove detergent residue and debris.
 - (1) Rinsing is extremely important, because residuals can reduce the efficacy of the disinfection and sterilization processes and possibly cause damage to the tissues of the surgical patient.
 - D. Scouring pads and abrasive cleaning agents should not be used for cleaning instruments and devices in order to prevent damage to the items.
 - E. Only brushes designated for use in cleaning instruments and devices should be purchased by the health care facility.
 - (1) Reusable brushes create a risk for cross-contamination. Reusable brushes should be cleaned and decontaminated at least daily or when heavily soiled. Brushes that show wear should be discarded.

- (2) Brushes used to clean instruments and devices with lumens must be the correct size. If the brush is too large, it will not properly fit into the lumen; if shoved into the lumen it could damage the instrument or device and possibly become stuck within. If too small, the brush will not make complete contact with the lumen's surface and prevent thorough cleaning.
- F. A three-sink method should be used for manual cleaning: A sink with tap water and detergent; second sink with tap water for rinsing; third sink with distilled/de-ionized water as a second rinse to aid in preventing staining.
3. The use of mechanical cleaning equipment is recommended as the primary method for decontamination of instruments and devices that can withstand the process. Mechanical cleaning equipment provides the advantage of exposing the instruments and devices to a microbicidal process.
 - A. The use of mechanical cleaning equipment significantly reduces the amount of contact time between the HCW and contaminated items.
 - B. Thermal disinfection can be accomplished with the use of washer-sanitizers, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Washer sanitizers provide the lowest level of disinfection, and washer-sterilizers offer the highest level of disinfection.
 - (1) Thermal disinfection should only be used to render items safe to handle by HCWs not wearing PPE and not as a process in which they are ready for reuse in surgery. Critical items should always be put through a sterilization process as well as semi-critical items should be either sterilized or high level disinfected.
 - (2) To ensure proper functioning of the equipment, routine maintenance should be performed according to the manufacturer's instructions, the strainer should be cleaned on a daily basis, and the operating instructions provided by the manufacturer should be followed.
 - (3) Time and temperature should be monitored and documented.
 - (4) HCWs must be careful when removing hot items from the equipment in order to avoid burns. The items may be wet with hot water. Additionally, water that drips on the floor may make it slippery; the water should be wiped from the floor.

Standard of Practice V

The issue of when to use the ultrasonic cleaner (UC) in the cleaning of instruments and devices should be determined by the health care facility.

1. The issue of when to use the UC is controversial and should be determined by the facility. Suggestions for timing of use include after the initial rinse and prior to mechanical cleaning, or after mechanical cleaning, which may include a sterilization cycle.
 - A. Instruments and devices are not considered safe for handling by HCWs, if the UC is used prior to mechanical cleaning since the UC cleans, but does not disinfect or sterilize the items.

2. To ensure proper functioning of the UC, routine maintenance should be performed according to the manufacturer's instructions and the operating instructions provided by the manufacturer should be followed.
3. Instruments and devices must be initially rinsed to remove gross debris prior to being placed in the UC.
4. Water in the UC should be changed every eight hours or when visibly dirty.¹⁶
5. It is recommended that a detergent be added to the water to increase the efficacy of the cleaning process. The detergent must be low foaming in order to prevent interference with the cavitation process of the UC.
6. The UC should be run on an empty cycle each time water is changed in order to degass.
7. Instruments and devices should be placed in trays designed for use in the UC.
 - A. Ratcheted instruments should be in the open position.
 - B. Instruments should not be densely packed in the tray or stacked.
 - C. Instruments of unlike metals should not be placed together in the same tray, eg, stainless steel instruments should not be placed with aluminum, copper or brass instruments.
 - D. Instruments or items that are chrome plated or ebonized, or contain plastic, cork, wood, glass, chrome or rubber should not be placed in the UC.
8. Instruments and devices should be rinsed and dried.
 - A. There are several models of UCs. A common model consists of three tanks: the first tank contains the water and detergent; second tank is used for rinsing; and the third tank is used for drying.

Standard of Practice VI

Instruments delivered to the decontamination area/room should be cleaned either manually, with use of automated washers or a combination of both.

1. The manufacturer's written instructions and recommendations for cleaning of instruments should be followed.
 - A. Manufacturers are responsible for providing the written instructions for the decontamination of instruments as well as the test results verifying the instruments can be effectively decontaminated without posing any harm to HCWs.
 - B. The instructions should be kept on file and accessible at all times by HCWs.
 - C. The written policies and procedures for the decontamination area should be based upon the manufacturer's written instructions. The policies and procedures should be kept on file and accessible at all times by HCWs.
2. HCWs in the decontamination room should confirm that instruments with more than one part have been disassembled. Hinged instruments and instruments with ratchets should be in the open position to allow the cleaning solutions to reach the serrations, ratchets and joints.
3. HCWs should not reach into the container holding the reusable sharps in order to avoid injury and contamination with blood and body fluids.

- A. It is recommended that the HCW use a device such as padded tongs to remove the sharps and place in a separate tray for decontamination.
4. Prior to decontamination, it is recommended that the instruments be pretreated with a preliminary cold water rinse or soak in cold water with or without a soil-dissolving enzymatic cleaner to remove gross blood, tissue and debris from the joints, serrations and lumens of instruments. Instruments with lumen should be thoroughly rinsed or soaked vertically.
5. After pretreatment instruments should be decontaminated either by hand cleaning or mechanically.
 - A. A low-foaming cleaning agent should be used. Cleaning agents that produce bubbles prevent thorough rinsing of the instruments.
 - B. When mechanically cleaned, vertical cylinders should be used for instruments with lumens to ensure complete contact of the cleaning solution with the inner surface.
 - (1) Vertically soaking and cleaning lumened instruments prevents air bubbles from forming.
 - C. Instruments of unlike metals should not be placed together in the same tray for processing, eg, stainless steel instruments should not be placed with aluminum, copper or brass instruments.
 - D. When cleaning by hand, a solution of warm water and low-foaming detergent should be used. The mixing instructions of the manufacturer of the cleaning agent should be followed. It is recommended that the cleaning solution be changed after each use, eg, set of instruments.
6. All instruments should be thoroughly rinsed to remove detergent residue.
7. The use of a water-soluble lubricant is recommended following decontamination.
 - A. The manufacturer's instructions for mixing and use of the lubricant should be used.
 - B. It should be confirmed that the lubricant is compatible with the use of sterilization. Lubricants that contain oil bases should not be used; the oil will prevent the sterilizing agent from fully contacting the surface of the instruments.
 - C. The tray with instruments should be fully immersed in the lubricant (commonly referred to as "milking the instruments" due to the white color of the solution) for the length of time recommended by the manufacturer of the lubricant and the manufacturer of the instruments.

Standard of Practice VII

New and repaired instruments should be inspected, decontaminated, and sterilized according to the manufacturer's written instructions prior to being placed in the surgery department's normal circulation of instrumentation.

1. New and repaired instruments should be inspected to assure all moving parts are in good working order including: the box lock, tips align as well as teeth if present; cutting edges of scissors are sharp and free of burs or other damage; screws are in place and not loose or stripped; and ratchets hold the instrument closed without springing open. If defects are found, the instrument(s) should be

- immediately shipped back to the manufacturer or instrument repair business to be repaired or replaced.
2. Manufacturer's written instructions should be followed if pretreating new instruments is required. Manufacturers may require pretreating in steam sterilization in order to harden the coating on the instruments prior to routine cleaning and sterilization.
 3. New and repaired instruments should be decontaminated according to the manufacturer's written instructions prior to sterilization to remove soil and debris related to the manufacturing, repair and shipping of the instruments.

Standard of Practice VIII

Loaner instruments should be inspected, decontaminated, and sterilized according to the manufacturer's written instructions prior to being used. Loaner instrumentation is defined as instruments or instrument sets borrowed from a vendor for surgical procedures that are returned to the vendor after use.⁹

1. Prior to receiving the loaner instruments, the health care facility should request a copy of the manufacturer's written instructions for decontaminating and sterilizing the instruments. This will allow the facility to identify instrumentation that requires special handling and determine if the facility decontamination equipment and machines will meet the recommendations of the manufacturer. Additionally this avoids delays in processing the instruments and therefore, avoids delaying the scheduled surgical procedure(s).
2. Loaner instruments should be considered contaminated upon receipt.
 - A. The first step when the instruments arrive is completing an inventory.⁹ The correct items and number of items should be confirmed. The equipment and instruments, including instrument trays that the instruments arrived in, should be inspected to assure all moving parts are in good working order including the box lock; tips align as well as teeth if present; cutting edges of scissors are sharp and free of burs or other damage; screws are in place and not loose or stripped; and ratchets hold the instrument closed without springing open. Defective instruments and equipment should be immediately documented and reported to the surgery department supervisor in order to avoid delaying the surgical procedures(s).
 - B. The use of an inventory sheet is recommended in order to protect the facility⁹ The HCW should log receipt of the loaner instrumentation and implants; the following is recommendations for the information to be included⁹:
 - (1) Date
 - (2) Time
 - (3) Signature of delivery person
 - (4) Initials of receiving person
 - (5) Surgeon's name
 - (6) Patient's last name
 - (7) Number of trays or instruments
 - (8) Number of implants

- (9) Verify types and numbers of instruments and implants
- (10) Document quality assurance check
- C. The loaner instruments should be decontaminated according to manufacturer's written instructions.
 - (1) If the instrument trays or packages are received still intact from a previous sterilization process, they must still be considered contaminated since the sterile storage conditions cannot be maintained during transport as well as the ability to verify the sterilization biological indicator tests.
- 3. The request for loaner instruments should be made well in advance of when the surgical procedure(s) are scheduled to allow time to inventory, inspect, and reprocess the instruments and/or implants. The use of loaner instruments require cooperation and collaboration between the vendor, surgery department personnel, and HCWs involved in the reprocessing of the instruments to assure a smooth transfer of the instruments from loaner to user and user back to loaner.

Standard of Practice IX

The decontamination room should be a room that is physically separate from areas where clean instruments, supplies and equipment are undergoing preparation for sterilization to prevent the risk of cross-contamination.

- 1. Scrub sinks and hand washing stations should not be used for cleaning instruments.⁹ Cleaning dirty instruments in the scrub or hand washing sink will contaminate the faucet, sides and bottom of the sink thus contributing to cross contamination when HCWs use the sinks for hand washing or performing the surgical hand and arm scrub.
- 2. The design and location of the decontamination room should take into consideration the need to centralize the process in one area, allow for efficient transportation of contaminated devices to and from the points of use, prevent cross contamination with clean areas, safety of HCWs, and meet OSHA requirements.
 - A. It is recommended that health care facilities consult the ANSI/AAMI Standard ST79:2006: "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities".² The document provides requirements and guidelines for decontamination areas/rooms. Additionally, the American Institute of Architects provides recommendations in its publication "Guidelines for Design and Construction of Health Care Facilities."
 - B. The following environmental controls should be maintained in the decontamination room:
 - (1) Six-10 air exchanges per hour
 - (2) The room should have a door that is kept closed with the exception of when contaminated instruments are being delivered in order to maintain negative pressure. Negative pressure cannot be maintained when the door is left open

- (3) The recommended room temperature varies from organization to organization; recommends 18° C to 22° C (64° F to 72° F).⁹
Low temperature aids in inhibiting the growth of microorganisms
- (4) Recommended relative humidity varies from organization to organization. IAHCMM recommends a range of 34% to 70%.⁹
- (5) Due to the use of chemicals in the cleaning of instruments and devices, an emergency eyewash station is required by OSHA.²⁶
The station should be positioned, so it is accessible within 10 seconds or 30 meters of potential chemical exposure.⁹
- (6) Hand wash stations should be provided per OSHA requirements for use after the HCW removes PPE.²⁷

Standard of Practice X

HCWs that handle contaminated instruments and devices are required to wear PPE to protect from soil and debris, blood and body fluids, and splashes from liquid chemical cleaning agents.

1. PPE should include
 - Hair cover
 - Eye protection
 - Fluid-resistant facemask
 - Fluid-resistant gown
 - Gloves
 - Shoe covers may be optional according to health care facility policy; however, they are recommended in the case of liquid chemical splashes
2. It is recommended that disposable hair cover, facemask, gown, gloves and shoe covers be worn.
3. A hand wash must be performed when the PPE is removed to prevent cross contamination and nosocomial infections.²⁷

Standard of Practice XI

HCWs involved in the handling and reprocessing of contaminated instruments and devices should complete initial education and training and competency validation on the use of decontamination processes and procedures, use of machines, chemicals used and PPE. Education and training should be an ongoing process in order to promote a safe environment for patients and HCWs.

1. Initial education and training should include, but not be limited to, the following:
 - PPE
 - Receiving of contaminated instruments and devices
 - Methods of decontamination
 - Chemical agents used at the health care facility to include location of Material Safety Data Sheets, location of manufacturer's written instructions, selection of cleaning agents according to instruments or devices to be cleaned, proper use and mixing/dilution of agents, safety precautions.

- Specific instructions for the decontamination of instrumentation and devices used at the health care facility
 - Procedures for decontaminating instruments contaminated by high-risk tissue (see Standard XII)
 - Procedures for decontaminating eye instrumentation
2. HCWs involved in the handling and reprocessing of contaminated instruments and devices should complete continuing education.
 - A. Education and training should be completed for the:
 - (1) decontamination of new instruments, equipment and devices.
 - (2) use of new decontamination equipment.
 - (3) use of new cleaning agents.
 3. HCWs involved in the handling and reprocessing of contaminated instruments and devices should be evaluated and competencies validated in the decontamination processes of instruments, devices and equipment. The validation records should be maintained by the health care facility and periodically updated.

Standard of Practice XII

Prior to assembly and packaging for sterilization, the instruments should be visually inspected for damage, debris, detergent residue, and all parts are present if the instrument was disassembled.

1. The following recommendations are general guidelines to follow for testing the functionality of instruments¹⁵:
 - A. Burs or cracks should not be present on the cutting edges of scissors. The scissor should close smoothly, and the blades be aligned. Scissors, excluding microscissors, should be sharp enough to cut two 4 x 4 sponges with little effort.
 - B. Ratcheted instruments should smoothly close and lock and not spring open when the ring handles are lightly tapped in the palm of the hand.
 - C. The jaws of hinged instruments should close evenly with no gaps, and the tips evenly lined.
 - D. Forceps should not be bent and easily close with the tips evenly lined. The teeth of tissue forceps should fit smoothly in the groove of the opposite side.
 - E. The ratchets on self-retaining retractors should be tested to ensure they remain in the open position and release with little effort.
 - F. Trocar points should be inspected for burs, cracks, dullness or bends.
2. Instruments that are not in proper working order should be removed and replaced in the instrument set.

Standard of Practice XIII

Manufacturer's instructions and health care facility policy should be followed for the use of colored tape and plastic dipping materials for the identification of specific surgical instruments.

1. Studies have confirmed that the use of colored tape does not interfere with the sterilizing agent contacting the underlying surface of the surgical instruments.²¹

2. Plastic dipping materials do not interfere with the sterilizing agent with the exception of “flashing instruments.” Due to the nylon or plastic material’s heat insulating properties, instruments that have plastic material used for identification purposes cannot be flashed sterilized.
3. Manufacturer’s instructions and recommendations for the use of their surgical instrument identification tape should be obtained and followed by the HCWs involved in the preparation of instruments for sterilization.²⁸
4. The following are recommended techniques for the application of tape to surgical instruments⁹:
 - A. HCW should clean the hands and fingers with alcohol to remove oils, grease, dirt and other debris prior to handling and applying the tape.
 - B. Alcohol should be used to wipe the site of the instrument where the tape will be applied in order to remove lubricant or moisture that can prevent the tape from sticking to the instrument.
 - C. The site for application of the tape should always be the shank of the instrument in order for the tape to lay flat and avoid any gaps. Tape should not be applied to the rings of the instrument since the rounded surface is not conducive to complete adherence of the tape to the instrument surface.
 - D. The tape should be cut at an angle to allow the edges to lay flat when applied to the shank of the instrument.
 - E. It is recommended to cut a length of tape that can be wrapped around the shank one-and-one-half times.
 - F. The tape should be applied with firm but gentle tension without stretching the tape.
 - G. After the tape has been applied, the instruments should be sterilized to allow the heat to bond the tape to the instruments.
 - H. If the tape becomes worn, discolored, and/or is peeling from the instrument it should be removed as soon as possible and replaced to avoid the tape from coming loose and entering a surgical wound.
 - (1) It is recommended that the health care facility purchase a commercial cutting tool that is designed specifically for removing tape from surgical instruments in order to protect the underlying surface of the instruments from damage.
5. Due to the technical nature of using a dipping or color coating process for the identification of instruments including required equipment and trained personnel, AST recommends the use of a third-party vendor that can offer the services to properly color code the instruments.

Standard of Practice XIV

Instruments that have been exposed to patients that are known or suspected to have Creutzfeldt-Jakob disease (CJD) should be decontaminated according to Association for the Advancement of Medical Instrumentation (AAMI) and/or World Health Organization (WHO) recommendations.^{8,31}

1. The cleaning and decontamination of devices that have been used on high-risk tissue (Table 1) and high-risk patients is controversial. The information presented below is based on the recommendations from the AAMI and WHO. The

recommendations published by the WHO in 1999 were a result of a presentation at a conference held in Geneva, Switzerland in March 1999, titled *WHO Consultation on Caring for Patients and Hospital Infection Control in Relation to Human Transmissible Spongiform Encephalopathies*.³¹ These recommendations have been the subject of much discussion and highly quoted by the Centers for Disease Control and Prevention (CDC) as well as in major health care journals.

The CDC stated it best in their January 2007 online article *Questions and Answers: Creutzfeldt-Jakob Disease Infection Control Practices* and serves as a good reminder for HCWs when reviewing the AAMI and WHO guidelines⁸:

Inactivation studies have not rigorously evaluated the effectiveness of actual cleaning and reprocessing methods used in health care facilities. Recommendations to reprocess instruments potentially contaminated with the CJD agent are primarily derived from in-vitro inactivation studies that used either brain tissues or tissue homogenates, both of which pose enormous challenges to any sterilization process. The World Health Organization (WHO) has developed CJD infection control guidelines that can be a valuable guide to infection control personnel and other health care workers involved in the care of CJD patients.

Table 1: Levels of Risk of Tissue³¹

Risk Category	Tissues, Secretions and Excretions	
High-Risk Tissue	Brain Spinal cord Eye	
Low-Risk Tissue	Cerebrospinal fluid (CSF) Kidney Liver Lung Lymph nodes Placenta Spleen	
No Risk Tissue	Adipose Adrenal gland Gingival tissue Heart muscle Intestine Peripheral nerves Prostate Skeletal muscles Testes Thyroid gland	Tears Nasal mucosa Saliva Sweat Serous exudate Breast milk Semen Urine Feces

2. Three parameters, as stated by AAMI, that are considered when recommending the decontamination procedures are²:
 - A. Risk of the patient for having a prion disease: High risk patients include the following:
 - (1) Diagnosed with a prion disease
 - (2) Diagnosed with progressive dementia with possible prion disease
 - (3) Family history of prion disease
 - (4) History of dura mater transplants
 - (5) Documented history of cadaver-derived pituitary hormone injection
 - (6) Identified as carrying the gene mutation that contributes to familial transmissible spongiform encephalopathies (TSE)
 - B. Classification of the level of infectivity of body tissues (Table 1).
 - C. Intended use of medical devices:
 - (1) Critical devices: Those that are used upon sterile tissue.
 - (2) Semicritical devices: Those that are used on nonintact skin or mucous membranes.
3. The following are based upon recommendations that apply to the decontamination of instruments contaminated with high-risk tissues from high-risk patients.²
 - A. It is of utmost importance that the CST keeps the devices moist during the surgical procedure and during transfer to the decontamination room to prevent the drying of high risk tissue on the device.
 - B. Devices, such as surgical instruments, that are constructed in such a manner that allows for effective cleaning procedures that result in the complete removal of tissue can be cleaned and prevacuum steam sterilized at 134° C (273° F) for 18 minutes or more or 121° C (250° F) to 132° C (270° F) for one hour in a gravity-displacement sterilizer.
 - C. For devices that are difficult to clean, it is recommended that they be destroyed. However, even though the destruction of devices is the safest method, it also may not be the most practical or cost effective for a health care facility. The recommended alternative is to clean the devices and decontaminate in the prevacuum steam sterilizer at 134° C (273° F) for 18 minutes or more or 121° C (250° F) to 132° C (270° F) for one hour in a gravity-displacement sterilizer or place in a container of sodium hydroxide (NaOH) for one hour. The devices are then cleaned, assembled, wrapped and sterilized by conventional methods.
 - D. Flash sterilization should never be used for reprocessing devices contaminated with high-risk tissue.
 - E. The health care facility should have a tracking system in place in order to recall devices that have been used on high-risk patients and high-risk tissue. The components of the tracking system should allow easy identification of the patient on which the devices were used, date used, procedure that was performed, and the surgeon's name. The devices should be assigned a unique number. For example, if the health care facility has two ophthalmology instrument trays, they should be numbered eye #1 and eye #2.

4. The following are based upon WHO recommendations that apply to the decontamination of instruments contaminated with high-risk tissues from high-risk patients.²⁹
 - A. All HCWs involved in the post-operative handling, transport, and re-processing of devices contaminated with high-risk tissue should be familiar with the health care facility policies and adequately trained.
 - (1) HCWs involved in the transport, disinfection and decontamination of instruments or surfaces exposed to high-risk tissues should wear single-use PPE, including gloves, mask, and eyewear, such as goggles.
 - B. It is of utmost importance that the CST keeps the instruments moist during the surgical procedure and during transfer to the decontamination room to prevent the drying of high risk tissue on the device.
 - (1) Instruments should be placed in a leak-proof container with tight-fitting lid that is labeled biohazard for transfer to the decontamination room. A HCW, who is familiar with the health care facility policies and trained in the transfer of instruments contaminated with high-risk tissue, should be responsible for the transport of the container.
 - C. Instruments targeted for disposal by incineration should be placed in a leak-proof container with tight-fitting lid labeled hazardous and immediately transported to the incinerator. A HCW, who is familiar with the health care facility policies and trained in the transfer of instruments contaminated with high-risk tissue, should be responsible for the transport of the container.
 - D. When a patient diagnosis has not yet been confirmed and to prevent the unnecessary destruction of expensive instruments, it is recommended that the health care facility quarantine the instruments until the final diagnosis of persons suspected of TSEs.
 - (1) Instruments should be decontaminated and then cleaned, assembled, wrapped and sterilized by conventional methods. A hazard label should be affixed to each package or instrument tray and stored in specially marked, rigid sealed containers to prevent the re-introduction of the instruments into the routine sterile storage of instruments. If TSE is disqualified as a diagnosis, the instruments may be placed in sterile storage for use.
 - E. There should be no delay in the cleaning and decontamination of instruments contaminated with high-risk tissue in order to minimize the drying of tissues, blood and body fluids.
 - F. Avoid mixing instruments used on low- to no-risk tissue with those items used on high-risk tissue.
 - G. Instruments to be processed in machines, such as the washer-sterilizer and ultrasonic cleaner, should be decontaminated by one of the methods described below prior to processing through these machines.
 - (1) Once the instruments have been processed the machines should be run through an empty cycle before any further routine use.

- H. Work surfaces in the decontamination room should be covered with disposable material that can be removed and incinerated. The surfaces should be thoroughly cleaned with a diluted solution of sodium hypochlorite (NaOCl); manufacturer's instructions should be followed for the mixing the diluted solution.
- I. The following is from the previously mentioned WHO report, *Annex III Decontamination methods for Transmissible Spongiform Encephalopathies*.³¹

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration. In some health care situations, as described in the guidance, one of the following less effective methods may be preferred. Wherever possible, instruments and other materials subject to re-use should be kept moist between the time of exposure to infectious materials and subsequent decontamination and cleaning. If it can be done safely, removal of adherent particles through mechanical cleaning will enhance the decontamination process.

The following recommendations are based on the best available evidence at this time and are listed in order of more to less severe treatments. These recommendations may require revision, if new data become available.

1. Incineration

- 1. Use for all disposable instruments, materials and wastes.
- 2. Preferred method for all instruments exposed to high infectivity tissues.

2. Autoclave/chemical methods for heat-resistant instruments

- 1. Immerse in sodium hydroxide (NaOH) (recommended concentration is 1N NaOH) and heat in a gravity-displacement autoclave at 121° C for 30 minutes; clean; rinse in water and subject to routine sterilization.
- 2. Immerse in NaOH or sodium hypochlorite (recommended concentration is 20,000 ppm available chlorine) for one hour; transfer instruments to water; heat in a gravity displacement autoclave at 121° C for one hour; clean and subject to routine sterilization.
- 3. Immerse in NaOH or sodium hypochlorite for one hour: remove and rinse in water, then transfer to pen pan and heat in a gravity displacement (121° C) or porous load (134° C) autoclave for one hour; clean and subject to routine sterilization.
- 4. Immerse in NaOH and boil for 10 minutes at atmospheric pressure; clean, rinse in water and subject to routine sterilization.
- 5. Immerse in sodium hypochlorite (preferred) or NaOH (alternative) at ambient temperature for one hour; clean; rinse in water and subject to routine sterilization.
- 6. Autoclave at 134° C for 18 minutes.

3. Chemical methods for surfaces and heat sensitive instruments

1. Flood with 2N NaOH or undiluted sodium hypochlorite; let stand for one hour; mop up and rinse with water.
2. Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution, and some additional benefit may be derived from the use of one or another of the partially effective methods.

4. Autoclave/chemical methods for dry goods

1. Small dry goods that can withstand either NaOH or sodium hypochlorite should first be immersed in one or the other solution (as described above) and then heated in a porous load autoclave at $\geq 121^{\circ}\text{C}$ for one hour.
2. Bulky dry goods or dry goods of any size that cannot withstand exposure to NaOH or sodium hypochlorite should be heated in a porous load autoclave at 134°C for one hour.

5. Notes about autoclaving and chemicals

Gravity displacement autoclaves: Air is displaced by steam through a port in the bottom of the chamber. Gravity displacement autoclaves are designed for general decontamination and sterilization of solutions and instruments.

Porous load autoclaves: Air is exhausted by vacuum and replaced by steam. Porous load autoclaves are optimized for sterilization of clean instruments, gowns, drapes, toweling, and other dry materials required for surgery. They are not suitable for liquid sterilization.

Sodium hydroxide (NaOH, or soda lye): Be familiar with and observe safety guidelines for working with NaOH. 1N NaOH is a solution of 40 g NaOH in one litre of water. 1N NaOH readily reacts with CO_2 in air to form carbonates that neutralize NaOH and diminish its disinfective properties. 10N NaOH solutions do not absorb CO_2 , therefore, 1N NaOH working solutions should be prepared fresh for each use either from solid NaOH pellets, or by dilution of 10N NaOH stock solutions.

Sodium hypochlorite (NaOCl solution, or bleach): Be familiar with and observe safety guidelines for working with sodium hypochlorite. Household or industrial strength bleach is sold at different concentrations in different countries, so that a standard dilution cannot be specified. Efficacy depends upon the concentration of available chlorine and should be 20,000 ppm available chlorine. One common commercial formulation is 5.25% bleach, which contains 25,000 ppm chlorine. Therefore, undiluted commercial bleach can be safely used. If solid precursors of hypochloric acid is available, then stock solution and working solutions can be prepared fresh for each use.

6. Cautions regarding hazardous materials

In all cases, hazardous materials guidelines must be consulted.

1. Personnel

NaOH is caustic but relatively slow acting at room temperature, and can be removed from skin or clothing by thorough rinsing with water. Hot NaOH is aggressively caustic, and should not be handled until cool. The hazard posed by hot NaOH explains the need to limit boiling to 10 minutes, the shortest time known to be effective.

Hypochlorite solutions continuously evolve chlorine, and so must be kept tightly sealed and away from light. The amount of chlorine released during inactivation may be sufficient to create a potential respiratory hazard, unless the process is carried out in a well-ventilated or isolated location.

2. Material

In principle, NaOH does not corrode stainless steel, but in practice some formulations of stainless steel can be damaged (including some used for surgical instruments). It is advisable to test a sample or consult with the manufacturer before dedicating a large number of instruments to decontamination procedures. NaOH is known to be corrosive to glass and aluminum. Hypochlorite does not corrode glass or aluminum and has also been shown to be an effective sterilizing agent; it is, however, corrosive both to stainless steel and to autoclaves and (unlike NaOH) cannot be used as an instrument bath in the autoclave. If hypochlorite is used to clean or soak an instrument, it must be completely rinsed from the surfaces before autoclaving. Other decontamination methods may need testing, or consultation with the manufacturer to verify their effect on the instrument.

J. The WHO sterilization and soaking recommendations created concerns as related to possible damage that could occur to autoclaves and instruments. As a result two studies that are frequently referred to by HCWs were completed and are briefly reviewed.

1. Brown and Merritt conducted a study of the use of containment pans and lids that contain caustic lids for autoclaving instruments.⁵ The pans were made of polypropylene, which is resistant to autoclave temperatures and NaOH. Even though the WHO recommends 30 minutes at 121° C, the study was performed in conditions of 135° C for one hour in a gravity displacement sterilizer using the liquids, slow exhaust cycle.
 - (a) The findings demonstrated that it is possible with the appropriate containment pans and lids to prevent escape of NaOH vapors in order to prevent damage to the autoclave.
 - (b) Additionally, the use of the gravity displacement sterilizer using the liquids, slow exhaust cycle is essential to prevent boiling.
2. Brown, Merritt, Woods, and Busick conducted research studying the effects of soaking instruments in a pan containing 1N NaOH and NaOCl.⁶

- (a) The findings demonstrated that soaking in NaOH had the least damaging effects on instruments, but soaking in NaOCl caused severe damage to some of the instruments.

Standard of Practice XV

Ophthalmic surgical instruments should be decontaminated according to (AAMI), American Society of Cataract and Refractive Surgery (ASCRS), and American Society of Ophthalmic Registered Nurses (ASORN) recommendations.¹

Toxic anterior segment syndrome (TASS) is an acute inflammatory condition of the anterior chamber of the eye and is a potential postoperative complication of cataract surgery. TASS is a result of substances being introduced into the eye during the procedure and can cause the patient to incur severe permanent injury to the intraocular tissue and possible loss of vision.²⁵ Substances and products that have been identified as causes of TASS include:

- Topical antiseptic agents²⁴
- Surgical glove powder¹²
- Anesthetic agents¹⁷
- Preservatives^{22,23}
- Intraocular lens¹⁹

The ability to control TASS related to the above list of substances and products is possible by product removal from the market and alerts by government health care agencies. However, most cases of TASS are linked to inadequate decontamination and sterilization of ophthalmic instrumentation.²⁵ Contributing factors include the following:

- Residue of ophthalmic viscosurgical devices (OVD)²⁰
- Residues of cleaning detergents on instruments⁴
- Degradation of brass containing surgical instruments from plasma gas sterilization¹⁴
- Residue of glutaraldehyde²⁹
- Steam impurities in the steam autoclave¹⁸

The following recommendations are based on the AAMI 2008 recommendations that are published as Annex N in the ANSI/AAMI ST79:2006 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* and the ASCRS and ASORN recommendations published in the frequently referenced article *Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments*.^{1,2}

1. The manufacturer's written instructions for the decontamination of ophthalmic instruments should be followed. The instructions should be kept on file and accessible at all times by HCWs.
2. The manufacturer's instructions for the use of cleaning detergents should always be followed. The instructions should be kept on file and accessible at all times by HCWs.

3. Adequate time should be provided for thorough cleaning, rinsing, inspection and sterilization of ophthalmic instruments, including anticipating the possibility of additional re-cleaning to remove residues and OVD that are visualized during inspection.
 - A. The procedures for decontaminating ophthalmic instruments should always be followed and corners should not be cut in order to save time or money.⁷
 - B. An adequate inventory of ophthalmic instruments should be maintained in the normal, sterile instrument inventory in order to meet the ophthalmic case load and provide adequate time for decontamination and sterilization.
 - C. Flash sterilization should not be used for the sterilization of ophthalmic instruments and instrument trays between procedures in order to save time or serve as a substitute for having a sufficient inventory of ophthalmic instrumentation to meet the health care facility's ophthalmic case load.¹
4. The CST should keep the instruments moist from point of use to transport to the decontamination room to prevent the drying of debris and OVD.
 - A. OVD solution can quickly dry and harden on instruments making it highly difficult to remove during the decontamination process.²⁵
 - B. During the procedure, the CST should carefully wipe the instruments with a damp, lint-free cloth. Many of the instruments are microsurgery instruments and are thus delicate; the CST must be careful in not bending the tips of forceps or causing misalignment, causing the locking mechanisms of needle holders such as Castroviejo needle holders to be misaligned, or bending delicate retractors.
 - C. Flushing instruments with lumens should not be performed in the operating room to prevent splashing of debris on the sterile field or aerolization of the debris. Thorough cleaning and flushing of lumens should be completed in the decontamination room. After cleaning, sterile water should be used to thoroughly flush the lumen; the sterile water should be expelled from the lumen directly into the drain and not into the rinse water. Sterile water removes the cleaning agent residue. Expelling the sterile water directly into the drain prevents instruments from being recontaminated with lumen debris when placed in the rinse water.
 - (1) When possible single-use disposable cannulas and tubing should be used and discarded at the end of the procedure. Lumens are difficult to clean and also present a challenge in visually inspecting to confirm the lumen is free of cleaning agents, debris and biofilm. Single-use items eliminate this challenge.
 - (2) Single-use items should not be processed and reused. However, if single-use items are to be re-used, the health care facility must use FDA-approved reprocessing methods.³⁰
 - D. During the procedure, the phacoemulsifier handpiece, irrigator/aspirator, including tips and lens inserters, should be wiped down by the CST with a damp, lint-free cloth. At the end of the procedure, the phacoemulsifier handpiece should be flushed with balanced saline solution before disconnecting from the unit. Immediate flushing at end of procedure

prevents the drying of material inside the hand piece, resulting in difficult removal during the decontamination process.

- E. Unless indicated otherwise by the manufacturer's directions for use (DFU), the CST should immediately immerse instruments in a basin of sterile water at the end of the procedure. Biofilm that adheres to the instruments' surfaces is difficult to remove if allowed to dry. Organic debris that is kept moist prevents the build-up of biofilm.
 - (1) During the procedure, if the CST is positive that an instrument will not be used again during the procedure, he/she may place the instrument into the basin of sterile water. The basin should be placed in an area on the sterile back table that is as far away from the operative field as possible and away from instruments that are needed to complete the surgical procedure.
- 5. Intraocular instruments should be processed separately from all other nonophthalmologic surgical instruments to reduce the potential for cross-contamination by the bioburden from the general instruments or residue from cleaning agents.²
- 6. The DFU for many intraocular instruments recommend or require the use of sterile-distilled or sterile-deionized water for cleaning the instruments. Unless stated differently in the manufacturer's DFU, rinsing with sterile-distilled or sterile-deionized water is required for the final rinse.²⁵
 - A. A copious amount of sterile-distilled or sterile-deionized water should be used, and the instruments thoroughly rinsed to remove all cleaning agents, soil and debris as well as removal of OVD.
 - (1) The water should be drained/discarded and only debris-free water used for rinsing the next set of instruments.¹
 - (2) The instruments should not be placed in a basin of water and agitated as the final rinse.¹ This will most likely not thoroughly remove the cleaning agents from the surface of the instruments and, upon removal from the basin, cleaning agent mixed in with the water will cling to the instruments.
 - B. If an ultrasound cleaner (UC) is used, the HCW should consult the manufacturer's DFU to identify instruments that should not be placed in the ultrasonic cleaner.¹ Gross soil and debris and OVD must be removed prior to placing the instruments in the UC. Unless stated differently in the manufacturer's DFU, cleaning in the UC should be with an EPA-registered disinfectant followed by a rinse with sterile or tap water to remove the cleaning agent.¹ The UC machine should be emptied, cleaned, rinsed, and dried after each use to remove the bioburden. An empty load to degass the UC should be run upon refilling.
 - C. Following the final rinse, instruments with lumens should be fully dried with filtered, compressed air.
 - D. When manually cleaning intraocular instruments, the following recommendations should be followed.
 - (1) Brushes, including pipe cleaners used to clean lumens, should be designated for the cleaning of intraocular instruments.

Manufacturer's DFU should be consulted in regard to the types of brushes to be used for each instrument.

- (2) Brushes used for cleaning intraocular instruments should be discarded after each use. If reused, they should only be used once and transported to the decontamination room for cleaning, high-level disinfection, and sterilization.
- E. Unless stated differently in the manufacturer's DFU, instruments should be wiped down with 70% - 90% ethyl or isopropyl alcohol before assembling for sterilization. Alcohol serves as another step in disinfecting the instruments.
7. Immediately after cleaning and prior to assembly and packaging for sterilization each instrument should be visually inspected for debris, biofilm, OVD, and damage under magnification.^{7,13} If necessary, re-cleaning and rinsing should be performed if debris and/or residue is still present on an instrument or instruments.
8. HCWs involved in the handling and reprocessing of contaminated ophthalmic instruments should complete initial education, training and competency validation on the use of decontamination processes and procedures, use of machines, and chemicals used specific to ophthalmic instrumentation. Education and training should be an ongoing process in order to promote a safe environment for patients and HCWs.
 - A. Initial education and training should include, but not be limited to, the following:
 - (1) PPE
 - (2) Receiving of contaminated ophthalmic instruments
 - (3) Methods of decontaminating ophthalmic instruments
 - (4) Specific instructions for the decontamination of ophthalmic instrumentation
 - B. HCWs involved in the handling and reprocessing of contaminated ophthalmic instruments should complete continuing education.
 - (1) Continuing education and training should be completed for the decontamination of new ophthalmic instruments, use of new decontamination equipment, use of new cleaning agents
 - C. HCWs involved in the handling and reprocessing of contaminated ophthalmic instruments should be periodically evaluated for performance and competencies validated in the decontamination processes. The validation records should be maintained by the health care facility and periodically updated.
9. A record-keeping system should be established by the health care facility to track cases of TASS, as well as for detecting TASS. Cases of TASS should prompt the facility to re-evaluate the procedures and processes for decontaminating intraocular instruments, as well as evaluate the performance of the HCWs, who are involved in cleaning the instruments.

Competency Statements

Competency Statements	Measurable Criteria
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<ol style="list-style-type: none"> 1. The CST and CFA has the knowledge and skills for implementing the principles of aseptic technique as applied to the decontamination and disinfecting of surgical instruments. 2. The CST and CFA are knowledgeable of the procedures and processes for decontaminating surgical instruments. 3. The CST and CFA has the knowledge and skills to use the chemical agents and machines for the decontamination of surgical instruments. 	<ol style="list-style-type: none"> 1. Educational standards as established by the <i>Core Curriculum for Surgical Assisting</i> and <i>Core Curriculum for Surgical Technology</i>.^{10,11} 2. The subjects of principles of aseptic techniques and decontamination and disinfection of instruments are included in the didactic studies as a student. 3. Students demonstrate knowledge of the procedures and processes of decontamination and disinfection in the lab/mock O.R. setting and during clinical rotation. 4. As practitioners, CSTs and CFAs practice the principles of aseptic techniques as applied to the decontamination and disinfection of surgical instruments. 5. CSTs and CFAs complete continuing education to remain current in their knowledge of decontamination and disinfection procedures in particular as related to CJD and TASS.
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