

Ensuring the Joint Commission Readiness for Instrument Processing

(A Continuing Education Self-Study Activity)



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Ensuring the Joint Commission Readiness for Instrument Processing

(A Continuing Education Self-Study Activity)

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This educational activity is intended for use as a stand alone self-study activity. We suggest you take the following steps for successful completion:

1. Read the overview and objectives to ensure consistency with your own learning needs and objectives.
2. Review the content of the self-study activity, paying particular attention to those areas that reflect the objectives.
3. Complete the Test Questions and compare your responses with the answers provided.
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ENSURING THE JOINT COMMISSION READINESS FOR INSTRUMENT PROCESSING

(A Continuing Education Self-Study Activity)

OVERVIEW

After completing this continuing education activity, the participant should be able to:

1. Describe how new standards have changed The Joint Commission surveyors' focus on surgical instrument sterilization.
2. State the OR nurse's role at six different points in the instrument flash sterilization process.
3. State the CPD's role to ensure best instrument care practices for instrument flash sterilization process.
4. List three things OR nurses and CPD should ask of instrument manufacturers to help improve compliance with AAMI, AORN, and The Joint Commission standards.

INTENDED AUDIENCE

This continuing education activity is intended for perioperative nurses, surgical technologists, Central Processing Department personnel, and other health care professionals who are interested in learning more about understanding the standards change and what needs to be done to comply with these standards of practice.

CREDIT/CREDIT INFORMATION

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The International Association of Healthcare Central Service Materiel Management has approved this educational offering for **1.0 contact hours** to participants who successfully complete this program.

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EXPIRATION DATE

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INTRODUCTION - AORN, AAMI, AND THE JOINT COMMISSION STANDARDS AND RECOMMENDED PRACTICES

The AORN Standards of Perioperative Nursing and Recommended Practices are developed to help professional perioperative nurses provide the highest levels of patient care.¹ These standards and recommended practices are developed by perioperative nurse specialists within AORN and in collaboration with other professional organizations such as the Association for the Advancement of Medical Instrumentation (AAMI); the recommended practices represent the Association's official position on questions regarding optimal perioperative nursing practice.² The Joint Commission (TJC) measures the hospital's compliance with standards and recommended practices during TJC surveys. Standards are continuously revised and updated to reflect new evidence and to address critical health care issues.

AORN

The AORN Standards of Perioperative Nursing Practice are consistent with American Nurses Association's "Standards of Nursing Practice" and "Standards of Professional Performance."³

The AORN recommended practices for perioperative nurses are developed by:⁴

- Perioperative nurse specialists in AORN Center for Nursing Practice;
- Selected members of the Association, i.e., Members of the Recommended Practices Committee; and
- Collaboration with liaisons from other professional organizations.

The recommended practices are based on:

- principles in nursing science;
- microbiology;
- research;
- review of the scientific literature; AND
- opinion's of knowledgeable experts.

It is important to note that compliance with the AORN recommended practices is voluntary. Application of the recommended practices in individual work settings requires careful review of existing policies and procedures; this review may indicate that new policies and/or procedures are needed. Within the context of the recommended practices, "may", "can", "should", and "must" are used to delineate the urgency of the recommended practice.

AAMI

The AAMI guideline, ANSI/AAMI ST79: 2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities was recently updated and outlines recommendations to guide health care personnel in the proper use of processing equipment.⁵

The AAMI Standards and Guidelines are developed in collaboration with other professionals, including global sterilization experts from industry, nursing, central sterile (CS), scientists, engineers, US Food and Drug Administration (FDA), quality assurance (QA), The Centers for Disease Control and Prevention (CDC), and other individuals. The objectives of developing AAMI standards include:

- a continued increase in the safe and effective application of current technologies to patient care; and
- the encouragement of new technologies.

It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation. They are based on:

- principles of sterilization;
- microbiology;
- evidence-based data;
- input, analysis and opinion of knowledgeable experts; and
- FDA, CDC, AORN, IACSHMM support.

Compliance with the AAMI guidelines is also voluntary. The recommended practices are applied to existing equipment, devices and technologies used in hospitals; “may”, “can”, “should” indicate strong recommendations; “must” is not used.

How They All Work Together

The Joint Commission measures the hospital's compliance to standards and recommended practices outlined by AORN and AAMI, as well as those issued by the FDA, CDC, and the International Association of Hospital Central Service Materials Management (IAHCSMM).

SURGICAL SITE INFECTIONS

In order to understand the importance of effective instrument sterilization practices, it is helpful to first review the statistics on surgical site infections (SSIs), as healthcare-associated infections, which are staggering.

Healthcare-associated infections (HAIs) are infections that patients acquire during the course of receiving treatment within a healthcare setting; they are one of the top ten leading causes of death in the United States.⁶ A new report from the Centers for Disease Control and Prevention (CDC) estimates that in American hospitals alone, healthcare-associated infections account for an estimated 1.7 million infections and 99,000 associated deaths each year. Of these HAIs, 22% are surgical site infections.⁷

Among surgical patients, SSIs were the most common nosocomial infection, accounting for 38% of all such infections; surgical site infections increase length of stay by 7 to 10

days.⁸ Furthermore, patients who develop SSIs are twice as likely to die, 60% more likely to spend time in an intensive care unit (ICU), and more than five times more likely to be readmitted to the hospital.⁹ The mean attributable cost of each surgical site infection is \$25,546 (ranging from \$1,783 to \$134,602), based on a review of studies published from 2001 to 2004, each examining the simple cost of the HAIs or evaluating the economics of an intervention to prevent or reduce HAIs.¹⁰

The increasing costs of treating SSIs were further affected in July 2008 when the Centers for Medicare and Medicaid Services (CMS) announced new Medicare and Medicaid reimbursement and coverage policies to improve safety for hospitalized patients.¹¹ The acute-care Inpatient Prospective Payment System's (IPPS) final ruling, which updated Medicare payments to hospitals for fiscal year 2009 provided additional incentives for health care facilities to improve the quality of care provided to Medicare patients by including payment provisions to reduce preventable medical errors that occur in health care facilities. Specifically, if a condition is not present upon admission, but is acquired during the course of the patient's hospital stay, Medicare no longer pays the additional costs of the hospitalization; moreover, the patient is not responsible for the additional costs and cannot be billed. Medicare has flagged all SSIs on its "no pay" list.

The good news is that SSIs are preventable and established recommended practices are readily available. Evidence-based practices include optimal disinfection of the surgical team's hands and optimal cleaning, disinfection and/or sterilization of surgical instruments.

NEW STANDARDS

As previously noted, AAMI, in collaboration with the American National Standards Institute (ANSI), has issued ANSI/AAMI ST79:2009, a new, comprehensive guide to optimal steam sterilization and sterility assurance in health care facilities. AORN advises perioperative nurses to review the AAMI standards for additional practice details. The ANSI/AAMI standard provides thorough detail on how to decontaminate, inspect, and make ready an instrument or tray for steam sterilization. The Joint Commission has historically measured the number of times instruments had been flashed, which was regarded as a practice outlier. However, in 2009, The Joint Commission will now measure the hospital's compliance to all the instrument processing steps recommended by ANSI/AAMI ST79:2009 and not limiting the survey to only the number of times an instrument was flash sterilized.

EXPANDED AUDITS BY THE JOINT COMMISSION

In keeping with the new standards for steam sterilization, including flash sterilization, The Joint Commission surveyors will focus on all of the critical steps and the integrity of the sterilization process. On site, surveyors will:¹²

- Observe instrument pathway from the time they leave one operating room to when they are returned to the next.

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- Ask health care workers to provide the manufacturers' instructions for instrument sterilization and also to describe and demonstrate how the instruments are being cleaned and decontaminated according to those written instructions.
 - Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.
 - Verify that staff members are wearing appropriate personal protective equipment (PPE).
 - Observe the sterilization process. The surveyor will ask for the manufacturer's instructions for the following items: the sterilizer, wrapping or packing, and the instruments.
 - Review sterilization logs. Surveyors will ask about parametric, chemical, and biological indicators.
 - Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

AORN RECOMMENDED PRACTICES

The following practices are recommended in AORN's Recommended Practices for Sterilization in the Perioperative Practice Setting to help ensure compliance with the ST79:2009 standards in regards to flash sterilization: ¹³

- Use flash sterilization only in selected clinical situations, in a controlled manner.
- Perform proper decontamination.
- Use manufacturer's instructions for use.
- Use closed sterilization trays as approved by the FDA.
- Monitor the cycles.
- Maintain documentation of cycle information and monitoring results.
- Utilize the appropriate biological indicators (BIs) and chemical indicators (CIs).
- Prevent contamination during transfer.
- Ensure appropriate staff training.

THE WORKER'S ROLE IN INSTRUMENT FLASH STERILIZATION

The following is a brief summary of Central Processing and the OR nurse's roles at each step of the flash sterilization process:

1. **Before an instrument is flashed** - Determine if other sets are available (for example, within the SPD process, in storage, or designated for a later case). Coordinate with the SPD to obtain the first available set that is in their process (decontamination, assembly, or sterilization), letting them know the time when it will be needed. **HINT:** A good rule of thumb is to estimate three hours for a tray to complete an SPD process.
2. **Clean the instruments** – Confirm that the instruments have been cleaned correctly, in accordance with the “Directions for Use” supplied by the equipment manufacturer. Instruments may require disassembly, special cleaning, and/or an enzymatic soak.
3. **Check instruments' working condition** – Confirm that all instruments have been inspected correctly and are in proper working order.
4. **Flash sterilize the instruments** - Verify that your sterilizer settings match those recommended by the instrument/device manufacturer. Use only containers that have been approved by the FDA for flash sterilization to maintain sterility during transport.
5. **Record the load** – Record that all sterilization parameters were met for the load.
6. **Transport instruments to room** - Follow the facility's procedure for transporting instruments to the room and transport in a container approved by the FDA for flash sterilization.

Helpful resources for complying with flash sterilization standards include instrument tracking systems, real-time locations systems (RLTS), manufacturers' central repositories of instructions, an area within the facility where all of the instructions are kept (hard copy or within a system), and manufacturer in-service programs to help educate on how to perform all instrument processing steps properly.

PATIENT SAFETY IMPERATIVE!

Why is it so important to follow these recommendations? With so many different manufacturers and different cleaning, inspecting, and sterilizing instructions, there can be confusion. Standards compliance helps ensure the high-priority of patient safety. By using these standardized recommendations, perioperative personnel will help ensure patient safety.

WHAT YOU SHOULD ASK FROM MANUFACTURERS

To comply with instrument care standards, you need to ask for and receive the following from your instrument and equipment manufacturers:

- Current and comprehensive Directions for Use (also called Instructions for Use).
- In-servicing to explain and demonstrate the proper use of products and services.
- New technologies that make these process changes easier to implement and enforce.

Be sure to ask any questions you have about information provided.

DEVELOP A PLAN OF ACTION

Create a plan of action today! The necessary actions include the following:

- Review the standard operating procedures for your institution.
- Know where the Directions for Use are located.
- Understand how to use all of the equipment.
- Address repairs before they become an issue.
- Schedule in-services for sterilizers, instruments and other equipment.
- ASK if something is not clear or missing.
- Be prepared for the next Joint Commission audit.

CONCLUSION

Prevention of surgical site infections is a key goal for the perioperative team. In today's dynamic health care environment, perioperative personnel must remain aware of both the clinical and economic implications of SSIs. One key infection prevention measure is the provision of sterile instruments and devices. Therefore, it is imperative that perioperative personnel remain aware of the current sterilization standards and recommended practices promulgated by various professional organizations and accrediting bodies. By following the steps outlined in this activity, you can help ensure the highest quality of care, patient and staff safety, and compliance with AORN, AAMI and The Joint Commission standards. Follow a validated, repeatable process; and provide actionable data for infection surveillance and continuous quality improvement.

GLOSSARY

Biological Indicator (BI)	A sterilization process monitoring device commercially prepared with a known population of highly resistant spores that test the effectiveness of the method of sterilization being used. The indicator is used to demonstrate that conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.
Chemical Indicator (CI)	A sterilization monitoring device used to monitor the attainment of one or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.
Flash Sterilization	A process designed for the steam sterilization of patient care items for immediate use.
Health Care-Associated Infection (HAI)	An infection acquired by patients during hospitalization, with confirmation of diagnosis by clinical or laboratory evidence. The infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the hospital.
Infection	The invasion and multiplication of microorganisms in body tissues that cause cellular injury and clinical symptoms.
Personal Protective Equipment (PPE)	Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury.

Sterile

The state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000.

Sterilization

A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to this very low number, it can never be reduced to zero.

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SUGGESTED READINGS

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