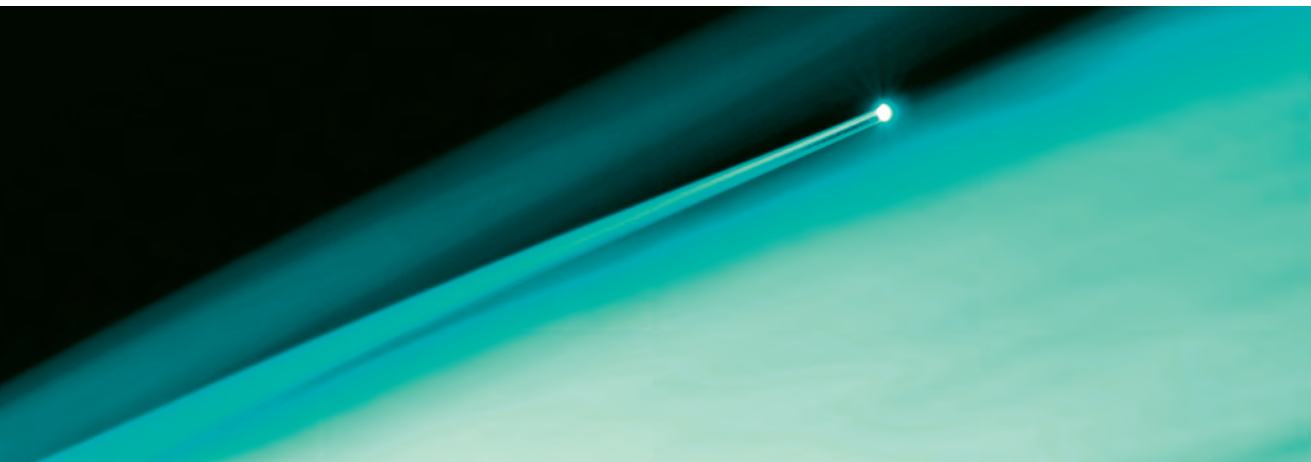


Sterile Processing In Healthcare Facilities Preparing for Accreditation Surveys



Rose Seavey

Sterile Processing In Healthcare Facilities: Preparing for Accreditation Surveys

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This publication is intended to be a helpful information resource,
and reflects the expert advice and views of the author.
It is not to be construed as an interpretation of AAMI standards,
nor does it constitute legal or regulatory advice.

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Dedication

To all of my colleagues fighting the good fight every day and following best practices in reprocessing reusable medical devices to make patient care safer.

Acknowledgments

While creating this manual, I had the great opportunity to work with Judy Veale, an exceptional editor. Judy is an extremely talented editor and researcher, and this book would not have been possible without her expertise, commitment, and guidance.

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Thank you,

Rose Seavey

Foreword

The purpose of this guidance document is to help healthcare professionals prepare for an accrediting agency survey as it relates to the sterile processing of surgical instruments and other medical devices in healthcare settings. Accreditation agencies include The Joint Commission (TJC), the Centers for Medicare & Medicaid Services (CMS), the American Association of Accreditation for Ambulatory Surgery Facilities (AAAASF), the Accreditation Association for Ambulatory Healthcare (AAAHHC), the Accreditation Commission for Health Care (ACHC), the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), the Community Health Accreditation Program (CHAP), DNV Healthcare (DNV), and state departments of health.

The accreditation process is designed to help healthcare facilities take a systems approach to evaluating their care processes and improving those processes for the betterment of patient care and safety. Each accreditation organization has accreditation standards and supporting documents that healthcare facilities can review before a survey. In general, the resources provided by accreditation organizations include all standards related to the healthcare facility as a whole. *Sterile Processing in Health Care Facilities: Preparing for Accreditation Surveys* summarizes the standards and associated documents related to the reprocessing of reusable medical devices.

This document contains valuable tools for preparing for accreditation surveys and maintaining compliance with accreditation requirements as they relate to sterile processing. These tools include information on accreditation organizations and requirements, information on relevant evidence-based guidelines published by professional organizations, a step-by-step guide to preparation for a survey, guidelines on risk reduction, and an example of a sterile processing auditing tool. New to this second edition are best-practices audit tools for intermediate-use steam sterilization (IUSS) and high-level disinfection (HLD).

CHAPTER 1

Introduction

Today's healthcare accreditation processes are conducted with a focus on the safety and quality of patient care. Sterilization and high-level disinfection (HLD) in healthcare facilities is a major focus of the accreditation survey process.

Various agencies and professional organizations perform accreditation surveys to evaluate healthcare facilities and the healthcare professionals practicing in those facilities. During the accreditation process, surveyors assess competency, ethics, and practices to verify that current published standards are being met. If a facility meets all the necessary requirements and is appropriately qualified, it passes the survey and is awarded a certification. The accreditation process, procedures, and requirements for certification vary depending on the accrediting organization and the type of facility (e.g., hospital, medical center, ambulatory care facility, physician's office, home care provider, medical laboratory).

Accreditation is a means of peer review by professionals (e.g., administrators, physicians, nurses, engineers) and is aimed at high standards that usually exceed state and federal requirements. Accreditation is a universally accepted means of enhancing the quality of healthcare. Many private insurers require accreditation as a condition of reimbursement. To qualify for federal funding for patients in Medicare and Medicaid programs, healthcare facilities must demonstrate that they comply with the government's hospital Conditions of Participation (CoP).

One of the key advantages of accreditation is the structure that is provided for improvement of performance and safety. When there is the expectation of the measurement of performance and safety by an accrediting organization, conformance to standards and recommended practices becomes more important to healthcare facilities. Recognized standards and recommended practices are built on sound principles, scientific research and data, and the opinions of experts in the field. Following these best practices helps to ensure the quality and safety of patient care. In addition, reimbursement is affected by accreditation or lack of accreditation; therefore, lack of accreditation can put a facility out of business.

In recent years, there has been an increased focus on infection prevention in healthcare. Healthcare professionals have increased their efforts to reduce healthcare-associated infections (HAIs), particularly surgical site infections (SSIs). The Joint Commission's (TJC's) National Patient Safety Goals (NPSGs) and national initiatives by the Centers for Disease Control and Prevention (CDC) and other organizations to reduce HAIs are two examples of why sterilization and HLD are under the spotlight with accreditation agencies. In addition, both TJC and the Centers for Medicare & Medicaid Services (CMS) have clarified their expectations regarding sterile processing in healthcare facilities.^{1,2}

This guidance document covers accreditation standards that pertain to sterilization and HLD in healthcare facilities, as well as the nationally accepted standards and recommended practices that constitute best practices in reprocessing. Accreditation by TJC and CMS will be covered in some depth. Accreditation programs focusing on ambulatory care facilities and sponsored by the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) and the Accreditation Association for Ambulatory Health Care (AAAHC) will also be discussed, as well as the accreditation programs of the Accreditation Commission for Health Care (ACHC), the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), the Community Health Accreditation Program (CHAP), and DNV Healthcare and the role of state health departments.

CHAPTER 2

Definitions and Abbreviations

Definitions

Biological indicators (BIs)³ Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.

Chemical indicators (CIs)³ Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or is used in specific tests of sterilization equipment.

Process challenge device (PCD)³ Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

Sterile³ Free from viable microorganisms.

Sterilization³ Validated process used to render a product free from viable microorganisms.

Abbreviations

AAAASF American Association for Accreditation of Ambulatory Surgery Facilities

AAAH Accreditation Association for Ambulatory Health Care

AAMI Association for the Advancement of Medical Instrumentation

ACHC Accreditation Commission for Health Care

ACSI APIC Consulting Services, Inc.

AER Automated endoscope reprocessor

ANSI American National Standards Institute

AO Accreditation organization

AOA American Osteopathic Association

AORN Association of periOperative Registered Nurses

APIC Association for Professionals in Infection Control and Epidemiology

APR Accreditation Participation Requirements

ASC Ambulatory surgery center

ASGE American Society for Gastrointestinal Endoscopy

CAH Critical access hospital

CAMAC *Comprehensive Accreditation Manual for Ambulatory Care*

CAMH *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*

CAMOB *Comprehensive Accreditation Manual for Office-Based Surgery Practices*

CDC Centers for Disease Control and Prevention

CDS Cleaning, disinfection, and sterilization

CFR <i>Code of Federal Regulations</i>	MOS Measure of success
CHAP Community Health Accreditation Program	MSDS Material safety data sheet
CJD Creutzfeldt-Jakob disease	NFPA National Fire Protection Association
CMS Centers for Medicare & Medicaid Services	NIAHO National Integrated Accreditation for Healthcare Organizations
CoP Conditions of participation	NIST National Institute of Standards and Technology
CVO Credentials verification organization	NPSG National Patient Safety Goal
DMEPOS Home/durable medical equipment suppliers	OPA Ortho-Phthalaldehyde
DNV DNV (Det Norske Veritas) Healthcare, an accrediting organization for health care facilities	OSHA Occupational Safety and Health Administration
EC Environment of care	PER Preliminary evidence report
EO Ethylene oxide	PPE Personal protective equipment
EP Element of performance	PPR Periodic performance review
FDA U.S. Food and Drug Administration	QC Quality Control
FMEA Failure modes and effects analysis	RCA Root cause analysis
FSA Focused standards assessment	RFI Requirements for improvement
HAI Healthcare-associated infection	RP Recommended practice
HFAP Healthcare Facilities Accreditation Program	SGNA Society of Gastroenterology Nurses and Associates
HFMEA Healthcare failure mode and effect analysis	SHEA Society for Healthcare Epidemiology of America
HHA Home health agency	SPD Sterile Processing Department
HLD High-level disinfection	SSI Surgical site infection
IAHCSMM International Association of Healthcare Central Service Materiel Management	SUDS Single-use devices
ICM Intracycle monitoring process	TEE Transesophageal echocardiogram
IFU Instructions for use	TJC The Joint Commission
ISO International Organization for Standardization	UP Universal Protocol
IUSS Immediate-use steam sterilization	VA U.S. Veterans Administration
MEC Minimum effectiveness concentration	WHO World Health Organization

CHAPTER 3

The Joint Commission

Overview

The Joint Commission (TJC) is an independent, nonprofit organization that accredits and certifies more than 18,000 healthcare organizations and programs in the United States, including approximately 88 percent of hospitals. “Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards.”⁴ TJC’s mission is “to continuously improve healthcare for the public, in collaboration with other stakeholders, by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.”⁴ TJC offers accreditation and certification for many types of healthcare organizations, including hospitals, doctors’ offices, nursing homes, office-based surgeries, behavioral health treatment facilities, and providers of home care services.

TJC’s accreditation process currently focuses on systems critical to the safety and quality of care, treatment, and services. Historically, the accreditation surveys were scheduled and facilities knew exactly when they would be visited by TJC. In 2006, TJC switched to an unannounced survey process. Facilities requesting accreditation and certification by TJC are still surveyed on a tri-annual (three-year) basis, but are not told when the survey will take place. This new process emphasizes continuous quality improvement and ongoing performance rather than survey preparation. Unannounced surveys are conducted 18 to 39 months after a facility’s previous full unannounced survey.⁵

Each year, TJC conducts an in-depth review of specific selected standards. During the review process, TJC takes into consideration new scientific literature, the opinions of experts, and feedback from organizations relating to all of their accreditation programs. TJC surveys are conducted according to national standards, local policy, and community standards, which include geographic and demographic standards.⁵

To begin the TJC accreditation and survey process, a healthcare facility must first submit an application and a Preliminary Evidence Report (PER) and pay a deposit of the applicable fees. After receipt and review of the application, a surveyor is assigned and sent to the healthcare facility. Appropriate healthcare staff are interviewed, and reviews are conducted. After the reviews are completed, the information is analyzed and the facility is given a score. To obtain or retain accreditation, organizations are required to score a minimum of 90% on “C” elements of performance and 100% on “A” elements of performance. A TJC accreditation is valid for three years. To maintain accreditation, a healthcare facility must undergo another survey process within three years.

At the end of the survey, facilities receive a preliminary report. The official report, with accreditation scores, is sent to the facility from TJC headquarters. The report includes requirements for improvement (RFI). The criticality of scoring is based on the relationship between the risk to patient care and the timeline for resolution. RFI that have a direct impact on patient care must be addressed within 45 days; for RFI that have an indirect impact on patient care, a facility will have 60 days in which to become compliant.⁵

Items that are not part of the TJC's charge include labor disputes, personnel disputes, pay issues, insurance or billing issues, and the facility's scope of practice. TJC will not serve as a mediator.⁵

Joint Commission Resources

Joint Commission Resources (JCR), a nonprofit affiliate of TJC, publishes the official handbooks used in the TJC survey process. The three handbooks that will be discussed here are as follows:

- *2014 Comprehensive Accreditation Manual for Hospitals: The Official Handbook (CAMH)*⁶
- *2014 Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)*⁷
- *2014 Comprehensive Accreditation Manual for Office-Based Surgery Practices (CAMOBS)*⁸

Accreditation manuals are also available for other healthcare facilities and services, such as primary care centers, home care, long-term care facilities, and clinical laboratories.

Hospital Accreditation Standards (CAMH)

The accreditation manuals are essential to understanding TJC accreditation standards. The accreditation standards for hospitals⁶ are organized into the following areas:

- Accreditation Participation Requirements (APR)
- Environment of Care (EC)
- Emergency Management (EM)
- Human Resources (HR)
- Infection Prevention and Control (IC)
- Information Management (IM)
- Leadership (LD)
- Life Safety (LS)
- Medication Management (MM)

- Medical Staff (MS)
- National Patient Safety Goals (NPSG)
- Nursing (NR)
- Provision of Care, Treatment, and Services (PC)
- Performance Improvement (PI)
- Record of Care, Treatment, and Services (RC)
- Rights and Responsibilities of the Individual (RI)
- Transplant Safety (TS)
- Waived Testing (WT)

Each standard is accompanied by elements of performance (EPs), and many include a rationale and introductory information. The standard is the goal, the rationale explains why the goal is important, and the elements of performance indicate the requirements associated with the goal. The EP scores are used to determine overall compliance with a standard. The EP scale for evaluation scores is:

0 – Insufficient compliance

1 – Partial compliance

2 – Satisfactory compliance

The CAMH handbook provides a self-assessment scoring grid for each EP.⁶ This tool can help facilities assess their potential score and therefore gauge their compliance with the standards.

Certain EPs have a related “measure of success” (MOS), a quantifiable measure that can be used to determine if an action has been effective and sustained. The MOSs are only used when a facility has not met an EP during a survey. The facility uses the MOS to show that a particular EP is now being met. MOSs are not used during the preparation for or conduct of a survey.

Since 2004, TJC has required accredited healthcare facilities to complete or update a Periodic Performance Review (PPR) annually. The PPR is a valuable self-assessment tool that enables facilities to determine their compliance with TJC standards, develop action plans to correct deficiencies, and be prepared for accreditation surveys. A facility is not required to share its PPR with a surveyor during a survey, but is required to submit it annually to TJC.

In 2013, TJC replaced the PPR process with an Intracycle Monitoring (ICM) process that includes a more narrowly defined Focused Standards Assessment (FSA). Whereas the PPR required self-assessment on all of the approximately 1,800 elements of performance in the CAHM, the FSA now requires hospitals to zero in on only 500 or so of the EPs. Included among the approximately 500 EPs subject to the FSA are direct impact



Documents

Document Sharing Hub

standards that TJC has determined to be “high risk,” along with all EPs that are part of the National Patient Safety Goals and any standard or EP that was found out of compliance during the hospital’s last triennial survey. The high-risk EPs and NPSGs are designated in the manual with an “R” notation in the margin next to the EP and the hospital’s extranet account will contain a listing of past survey findings.

In addition to the standards and EPs in the applicable accreditation manual, accredited organizations must also comply with answers stipulated in the *Frequently Asked Questions* that are published, updated periodically, and available for viewing at the Joint Commission’s website (www.jointcommission.org). The detail contained in the answer to a FAQ is often the missing link to understanding how to comply with a vaguely worded element of performance.

Annex A provides the TJC standards and EPs most relevant to sterile processing in hospitals.

Ambulatory Care Accreditation Standards (CAMAC)

The CAMAC manual is a very helpful resource for ambulatory surgery centers seeking to achieve or maintain continuous compliance with the Joint Commission’s requirement.

The accreditation standards, rationale statements, and EPs for ambulatory care facilities are organized similarly to those for hospitals.⁷ In most cases, the requirements are essentially the same, sometimes with slight modifications to take into account the different settings.

The accreditation standards for ambulatory surgery centers are organized into the following areas:⁷

- Accreditation Participation Requirements (APR)
- Environment of Care (EC)
- Emergency Management (EM)
- Human Resources (HR)
- Infection Prevention and Control (IC)
- Information Management (IM)
- Leadership (LD)
- Life Safety (LS)
- Medication Management (MM)
- National Patient Safety Goals (NPSG)
- Provision of Care, Treatment, and Services (PC)
- Performance Improvement (PI)

- Record of Care, Treatment, and Services (RC)
- Rights and Responsibilities of the Individual (RI)
- Transplant Safety (TS)
- Waived Testing (WT)

Annex B provides the TJC standards and EPs most relevant to reprocessing in ambulatory care facilities.

Office-Based Surgery Practice Accreditation Standards (CAMOBS)

The CAMOBS manual is a one-stop resource to help office-based surgery practices achieve or maintain continuous compliance with the Joint Commission’s requirements. The material in this manual will help guide process development and provide the highest quality of safe care, treatment, and services.

The accreditation standards, rationale statements, and EPs for office-based surgery practice are organized similarly to those for ambulatory care facilities. In most cases, the requirements are essentially the same, sometimes with slight modifications to take into account the differences between settings.

The accreditation standards for office-based surgery are organized into the following areas:

- Accreditation Participation Requirements (APR)
- Environment of Care (EC)
- Emergency Management (EM)
- Human Resources (HR)
- Infection Prevention and Control (IC)
- Information Management (IM)
- Leadership (LD)
- Life Safety (LS)
- Medication Management (MM)
- National Patient Safety Goals (NPSG)
- Provision of Care, Treatment, and Services (PC)
- Performance Improvement (PI)
- Record of Care, Treatment, and Services (RC)
- Rights and Responsibilities of the Individual (RI)
- Transplant Safety (TS)
- Waived Testing (WT)

Annex C provides the TJC standards and EPs most relevant to reprocessing in office-based surgery facilities.

TABLE 1 National Patient Safety Goals for Hospitals for 2014*

Goal 1	Improve the accuracy of patient identification.
Goal 2	Improve the effectiveness of communication among caregivers.
Goal 3	Improve the safety of using medications.
Goal 4	No longer applicable as a National Patient Safety Goal.
Goal 5	No longer applicable as a National Patient Safety Goal.
Goal 6	Reduce the harm associated with clinical alarm systems.
Goal 7	Reduce the risk of healthcare-associated infections. NPSG.07.01.01: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines. NPSG.07.03.01: Implement evidence-based practices to prevent healthcare-associated infections due to multidrug-resistant organisms in acute care hospitals. NPSG.07.04.01: Implement evidence-based practices to prevent central line-associated bloodstream infections. NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections. NPSG.07.06.01: Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).
Goal 8	Moved to NPSG.03.06.01.
Goal 9	Reduce the risk of patient harm resulting from falls.
Goal 10	No longer applicable as a National Patient Safety Goal.
Goal 11	No longer applicable as a National Patient Safety Goal.
Goal 12	No longer applicable as a National Patient Safety Goal.
Goal 13	No longer applicable as a National Patient Safety Goal.
Goal 14	No longer applicable as a National Patient Safety Goal.
Goal 15	The hospital identifies safety risks inherent in its patient population.
Goal 16	No longer applicable as a National Patient Safety Goal.

* Excerpted from: National Patient Safety Goals Effective Jan. 1, 2014. Hospital Accreditation Program. Copyright 2013. The Joint Commission. Reprinted with permission.

National Patient Safety Goals

To help accredited organizations address specific areas of concern in regard to patient safety, TJC established the National Patient Safety Goals (NPSGs) in 2002. The NPSGs are reviewed and updated each year and are targeted to areas known to be problematic in healthcare facilities according to the current medical safety literature.

In 2012, TJC approved one new NPSG, related to catheter-associated urinary tract infections, for hospitals. In 2013, a new NPSG on clinical alarm safety (NPSG.06.01.01) was approved for hospitals. The new goal will be implemented in two phases, one beginning Jan. 1, 2014, and one beginning Jan. 1, 2016.⁹

Associated with each NPSG are EPs that have been developed on the basis of evidence-based studies and expert opinion. The

CAMH includes a chapter that provides guidance on how to comply effectively with the EPs for each goal. Table 1 shows the NPSGs for hospitals for 2014.¹⁰ Goal 7 is of most direct relevance to reprocessing and is given in detail.

When TJC feels that the vast majority of hospitals have incorporated practices defined in a safety goal, that NPSG is removed from the annual list. However, no NPSG is ever deleted; instead of being on the annual list, it is incorporated into TJC standards.

TJC develops NPSGs for all of the healthcare programs that it accredits and certifies. This publication will discuss the safety goals developed for hospital, ambulatory care, and office-based surgery facilities. Table 2 shows the applicable NPSGs for ambulatory care facilities,¹¹ and Table 3 shows the applicable NPSGs for office-based surgery facilities.¹²

TABLE 2 National Patient Safety Goals for Ambulatory Care Facilities for 2014*

Goal 1 Improve the accuracy of patient identification.

Goal 3 Improve the safety of using medications.

Goal 7 Reduce the risk of healthcare-associated infections.

NPSG.07.01.01: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections.

* Excerpted from: National Patient Safety Goals Effective Jan. 1, 2014. Ambulatory Health Care Accreditation Program. Copyright 2013. The Joint Commission. Reprinted with permission.

TABLE 3 National Patient Safety Goals for Office-Based Surgery Facilities for 2014*

Goal 1 Improve the accuracy of patient identification.

Goal 3 Improve the safety of using medications.

Goal 7 Reduce the risk of healthcare-associated infections.

NPSG.07.01.01: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections.

* Excerpted from: National Patient Safety Goals Effective Jan. 1, 2014. Office-Based Surgery Accreditation Program. Copyright 2013. The Joint Commission. Reprinted with permission.

The NPSG most important for any healthcare facility that reprocesses reusable medical devices is NPSG.07.05.01 (“Implement evidence-based practices for preventing surgical site infections”). Meeting this goal means that the organization is following the most current CDC guidelines and the standards and recommended practices published by professional organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN). The EPs most pertinent to sterile processing are:¹⁰

- **EP 3:** Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).
- **EP 4:** As part of the effort to reduce surgical site infections:
 - Conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.
 - Select surgical site infection measures using best practices or evidence-based guidelines.
 - Monitor compliance with best practices or evidence-based guidelines.
 - Evaluate the effectiveness of prevention efforts.

Note: Surveillance may be targeted to certain procedures based on the hospital’s [organization’s] risk assessment.

Universal Protocol

Other elements important to TJC include assessing whether facilities have implemented a specific code of behavior to reduce the occurrence of sentinel events. TJC created a set of rules called the Universal Protocol (UP) to address the continuing occurrence of wrong-site, wrong-procedure, and wrong-person

surgery and other procedures in TJC accredited organizations. The Universal Protocol drew on, expanded, and integrated a series of requirements under the 2003 and 2004 NPSGs. The three principal components of the Universal Protocol are a preprocedure verification, site marking, and a time-out.¹³

The TJC originally approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™ in July 2003, and it became effective July 1, 2004, for all accredited hospitals, ambulatory-care, and office-based surgery facilities.¹³

The Universal Protocol is applicable to all surgical and nonsurgical invasive procedures. The principles behind the UP include the following:

- Prevention of wrong-person, wrong-site, and wrong procedures
- A robust approach to always conducting the correct procedure on the correct person at the correct site
- Active involvement and improved communication among all procedure team members
- Consistent implementation of a standardized process

Table 4 shows the Universal Protocol for hospital, ambulatory care, and office-based surgery facilities for 2014.^{10,11,12}

In 2010, AORN created a Comprehensive Surgical Checklist¹⁴ to support a facility’s need to use a single checklist that includes both the safety checks outlined in the World Health Organization’s (WHO’s) Surgical Safety Checklist and the safety checks specified in TJC’s Universal Protocol. The AORN checklist is useful for all types of facilities: hospital operating rooms (ORs), ambulatory surgery centers (ASCs), and physicians’ offices. See Annex D.

Two important elements of the time-out portion of the UP and Comprehensive Surgical Checklist relate to the sterilization and HLD of surgical instruments and equipment: The surgical procedure team should ask if there are any concerns about

TABLE 4 Universal Protocol for Hospital, Ambulatory Care, and Office-Based Surgery Facilities for 2014*

UP.01.01.01	Conduct a preprocedure verification process.
UP.01.02.01	Mark the procedure site.
UP.01.03.01	A time-out is performed before the procedure.

* Excerpted from: National Patient Safety Goals Effective Jan. 1, 2014. Hospital Accreditation Program. Copyright 2013. The Joint Commission. Reprinted with permission.

instruments or equipment, and the scrub and circulation nurses should ensure that all sterilization indicators and other monitors have been confirmed.

The AORN comprehensive checklist recommends identifying issues or concerns relating to instruments or equipment four times, including:¹⁴

1. Preprocedure check-in: “Any special equipment, devices or implants”
2. Sign-in, briefing: “All members of the team have discussed care plan and addressed concerns.”
3. Time-out: “Any equipment concerns?”
4. Sign-out: “Any equipment problems to be addressed?”

Tracers

A TJC on-site accreditation survey typically includes a “tracer,” in which surveyors follow the course of treatment of a specific patient in order to assess the healthcare facility’s compliance with specific standards. An individual patient’s record serves as a road map for the surveyors as they move through the healthcare facility. Tracers help the surveyors identify performance issues associated with a particular process or the interface between processes. There are three types of tracers:⁶

- **Program-specific tracers**, which are intended to identify safety concerns within various levels and types of care, treatment, or services. Surveyors evaluate program-specific issues and compliance with relevant standards that affect patient safety.
- **System tracers**, which involve interactions between surveyors and relevant staff members to trace a system within the facility. Surveyors evaluate a system or process with respect to how related processes are integrated and how disciplines and departments communicate and are integrated.
- **Individual tracers**, which track the care of individual patients. Surveyors analyze a facility’s system of providing care, treatment, and services using real patients for assessment of standards compliance. During an on-site individual tracer, surveyors examine individual components of a system and how they function and interact with each other.

When conducting an *individual tracer*, the surveyors will:⁶

- Follow the course of a type of care, treatment, and service provided to the patient by the hospital

- Assess the interrelationships among disciplines and services/ programs and the important functions in the care, treatment, or services provided
- Evaluate the performance of processes relevant to the care, treatment or service needs of the patient, with particular focus on the integration and coordination of distinct but related processes
- Identify vulnerabilities in the care process

Individual-based *system tracers* focus on high-risk processes across the healthcare facility. Individual system tracers determine standards compliance as it relates to the delivery of individual patient care. The surveyors evaluate the performance of important patient-related functions across the facility. The three individual-based system tracers are data use, infection control, and medical management.⁶

Program-specific tracers are performed at the discretion of the surveyors, depending on the type of facility being surveyed.⁶

The use of tracer methodology in sterile processing is discussed in detail in Chapter 8.

TJC Focus on Cleaning, Disinfection, and Sterilization

Sterile processing involves the use of many types of cleaning, disinfection, and sterilization equipment. There are numerous guidelines (e.g., ANSI/AAMI ST79³) addressing the design and maintenance of the workplace to ensure effective and efficient processing, promote personnel safety, reduce environmental contamination, and preserve the sterility of processed items. TJC has standards and EPs addressing the management of the environment of care and the management of information that relates to these issues. (See Annexes A, B, and C for the TJC standards and EPs that relate to the environment of care.)

For patient safety, all healthcare personnel involved in reprocessing items for patient use should be knowledgeable in all aspects of the sterilization process. Leadership is responsible for ensuring that staff have appropriate training, education, and competence to perform the tasks associated with sterilization. TJC’s standards and elements of performance (EPs) addressing infection prevention and control, human resources, and leadership, as they relate to reprocessing in hospitals, ambulatory care facilities, and office-based surgery facilities, are provided in Annexes A, B, and C.

On June 15, 2009, TJC announced an update of its position on steam sterilization. In “Steam Sterilization—Update on The Joint Commission’s Position,” TJC discussed decisions made by TJC regarding sterilization that have an impact on the interpretation of accreditation standards and, consequently, the survey process.¹

The TJC statement focused primarily on flash sterilization (now termed “immediate-use steam sterilization” [IUSS] in most published professional standards and guidelines), but the critical steps outlined in the document are relevant to all types of sterilization processes:

- Cleaning and decontamination
- Sterilization
- Storage or return to the sterile field

Surveys will now be focused on whether the facility is using a complete and effective sterilization process, rather than on the particular cycle or method used. That is, the surveyor will be looking at breaches in the process. For example, the surveyor might ask why certain instruments are being routinely processed by IUSS and what is being done to resolve the issue. It is the ability of the facility to identify abuses in the process and resolve issues found that is the key to compliance.

To determine if the process is appropriate, TJC surveyors will review all of the critical aspects of disinfection and sterilization practices throughout the facility. The surveyor will be looking for the integrity of the sterilization process as a whole and performing the following activities:

- Track instruments from the time they are used in an operating room until they are returned for the next use.
- Ask personnel to provide manufacturers’ written instructions for reprocessing of instruments and to describe and demonstrate how instruments are being processed according to those instructions.
- Observe instrument cleaning.
- Verify that processing personnel are wearing appropriate personal protective equipment (PPE).
- Observe the sterilization process and request manufacturers’ written instructions for operating the sterilizer, packaging instruments, and sterilizing instruments.
- Review sterilization records and verify the use of sterilization process indicators such as physical monitors, chemical indicators (CIs), and biological indicators (BIs).

- Observe the transport of sterile instruments to the operating room and verify that they are protected from contamination.
- Under this new survey process, it can be expected that facilities might be cited for the following deficiencies:¹⁵
 - Using IUSS frequently for the same items
 - Not collecting data on when IUSS is used
 - Not taking action on the basis of IUSS usage data to reduce IUSS of particular items
 - Not having a quality process
 - Failing to follow the manufacturer’s written instructions for use (IFU)
 - Failing to adequately clean instruments
 - Failing to use monitoring devices appropriately (e.g., physical monitors, chemical and biological indicators, process challenge devices [PCDs])
 - Transporting uncovered instruments to the point of use

A multi-society statement on IUSS, which further identifies best practice with respect to IUSS, has recently been issued by a number of professional organizations (Annex E).

In presentations at the 2012 and 2013 Annual Conference and Expo of the International Association of Healthcare Central Service Materiel Management (IAHCSMM),^{5,16} TJC surveyor John Eiland indicated that surveyors will be assessing three types of staff competencies: demonstration, certification, and involvement with professional associations. They will look for job descriptions that match responsibilities, documented skills checklists, and training-based annual evaluation forms. Surveyors will want to establish whether the facility is following national and local standards. This assessment applies to any areas of the facility that have sterilizers, such as labor and delivery departments, operating rooms, and sterile processing areas.

Mr. Eiland also stated that TJC considers sterile processing personnel to be the subject matter experts throughout the facility and off-site clinics. Sterile processing managers should set the standards for reprocessing, and these standards, including record-keeping, should be the same in all areas of the healthcare system or facility where reprocessing is performed (e.g., labor and delivery, endoscopy clinics). Sterile processing personnel should be involved in the facility’s disaster planning, particularly regarding the loss of water or electrical power.

TJC will have an engineer on site for two days, and the engineer will almost certainly tour sterile processing. The engineer will review the sterile processing area for compliance with *Life Safety Code* requirements found in NFPA 101.¹⁷ Additional environmental concerns include temperature and humidity control, water quality, the presence of eyewash stations, appropriate ventilation (air exchanges, positive and negative air flow), separation of clean and dirty areas, and traffic control. The TJC surveyors will want to see that the facility complies with ANSI/AAMI ST79.³ (Annex F of this book provides key provisions of ANSI/AAMI ST79 in relation to accreditation surveys and identifies TJC standards pertinent to each section of ANSI/AAMI ST79.) Although ANSI/AAMI ST79 covers steam sterilization, it is considered to be applicable across the entire reprocessing spectrum within the facility. Surveyors will review equipment cleaning and maintenance records. Endoscope cleaning and processing areas and work processes will be a high priority. TJC considers reprocessing to be critical to the facility's mission and function.⁵

Surveyors will also review the following:^{5,16}

- Sterilization records (e.g., cycle parameters, recalls, results of both positive-control BIs and test BIs)
- The exception forms for premature release of implantable devices and documentation of who authorized the premature release of implantables before the BI results were available

NOTE: An example of such an exception form is provided in Annex L of ANSI/AAMI ST79.

- The tracking of instruments to patients
- How long sterilization records are kept on file
- The types of sterilization cycles used and whether all types of cycles used are routinely monitored with a BI PCD
- Whether the appropriate BIs and PCDs are used
- Whether the positive-control and load BIs have the same lot number
- Whether sterilization load labels are adequate for purposes of potential recalls
- Whether double peel-pouching is performed correctly

Mr. Eiland also noted that all aspects of quality control, including HLD quality control test strips, continue to be one of TJC's top ten priorities.^{5,16}



CHAPTER 4

Centers for Medicare And Medicaid Services

Overview

The Medicare and Medicaid programs were signed into law on July 30, 1965, by President Johnson. These programs are administered by the Centers for Medicare and Medicaid Services.

If a healthcare facility wishes to participate in Medicare, it must meet the standards specified in Title 42, Parts 416, 418, 482, 484, or 485 (as applicable) of the *Code of Federal Regulations* (CFR) and receive accreditation from an accreditation organization (AO) that CMS has approved as a “deeming authority.” As of April 2012, the CMS-approved AOs are as follows:¹⁸

- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)
- Community Health Accreditation Program (CHAP)
- DNV Healthcare (DNV)
- The Joint Commission (TJC)

Before receiving deeming authority for Medicare, an AO must apply and must demonstrate its ability to meet or exceed the Medicare conditions of participation/coverage specified in the CFR:¹⁹

- Ambulatory surgical centers (ASCs) in accordance with 42 CFR 416
- Critical access hospitals (CAHs) in accordance with 42 CFR 485, Subpart F
- Home health agencies (HHAs) in accordance with 42 CFR 484
- Hospices in accordance with 42 CFR 418
- Hospitals in accordance with 42 CFR 482
- Organizations that provide outpatient physical therapy and speech language pathology services (OPTs) in accordance with 42 CFR 485, Subpart H
- Psychiatric hospitals in accordance with 42 CFR 482
- Rural health clinics (RHCs) in accordance with 42 CFR 491



CMS and Sterile Processing

Ambulatory Surgery Centers

On Sep. 4, 2009, CMS released a memo to state survey agency directors clarifying CMS's position on flash sterilization for ASCs, which rely heavily on this sterilization process.² (Flash sterilization is now termed "immediate-use steam sterilization" in most published professional standards and guidelines.) The memo declared that "state survey agencies (SAs) using the new survey process in FY 2009, including completing the Infection Control Surveyor Worksheet, have experienced challenges in evaluating use of 'flash sterilization' by ASCs."²

With assistance from the CDC and the Food and Drug Administration (FDA), CMS developed a set of questions for surveyors to use to assess the appropriateness of the ASC sterilization practices. The questions that surveyors will ask are as follows:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used, is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?

The CMS considers routine sterilization of unwrapped/uncontained loads a violation of 42 CFR 416.51(a).²

Following the manufacturer's current written instructions is critical. The CMS puts an emphasis on facilities having and following the validated, FDA-cleared manufacturer's written IFU. The weight of the instrument set, the complexity of the devices, the presence or absence of fabric, the presence or absence of lumens, and other factors all influence sterilization outcome. "If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC's practices should be cited as a violation of 42 CFR 416.44(b)(5)."²

The memo also emphasizes the importance of cleaning: "Of course, no item can be successfully sterilized if it has not first been thoroughly cleaned, so surveyors should also observe whether adequate pre-cleaning is being performed with water and detergent or water and enzymatic cleaners prior to sterilization. Cleaning can be either manual or mechanical."²

The CMS later updated the ASC worksheet, which became effective on Nov. 24, 2010. The Ambulatory Surgery Center Infection Control Surveyor Worksheet is available online (www.cms.gov/manuals/downloads/som107_exhibit_351.pdf) and is provided here as Annex G. This worksheet lists items that must be assessed during the on-site survey to determine compliance with infection Conditions for Coverage. It states that "the interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (e.g., staff person responsible for sterilization should answer the sterilization questions)."²⁰

Section III, "Single Use Devices, Sterilization, and High Level Disinfection," of Part 2 (Infection Control & Related Practices) of the worksheet states the following:²⁰

Pre-cleaning must always be performed prior to sterilization and high-level disinfection.

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments).

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades).

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

The worksheet lists the ways that surveyors should assess the practices covered in each section and can be a very helpful tool for ASCs when they prepare for an accreditation survey.

Hospitals

On Oct. 14, 2011, the CMS issued a memorandum as part of a general U.S. Department of Health and Human Services initiative, the *Partnership for Patients, Better Care, Lower Costs (P3P)*. The memorandum stated that CMS will be using three new surveyor worksheets, in draft form, to assess compliance with hospital CoPs for Quality Assessment and Performance Improvement, Infection Control, and Discharge Planning.²¹



The three draft worksheets were updated and appended to a subsequent CMS memorandum issued May 12, 2012.²² This memorandum stated that the revised worksheets would be tested in a pilot program on the assessment of the aforementioned CoPs and that there could be additional changes to the worksheets.

According to the revised draft worksheets, specific policies and procedures might be reviewed during a survey, depending on concerns or observations. It is expected that infection control policies and procedures will be developed and written in accordance with nationally recognized guidelines and applicable state and federal law.²² ANSI/AAMI ST79³ is the document that TJC surveyors are now using for reference, and it is likely that CMS surveyors will use it as well. Chapter 6 discusses this and other standards published by AAMI, as well as the standards, recommended practices, and guidelines of AORN, APIC, SGNA, the CDC, and other organizations.

The draft CMS surveyor worksheet, “Assessing Hospital Compliance with the Conditions of Participation for Infection Control,” consists of five modules:²²

- Module 1: Infection Control/Prevention Program
- Module 2: General Infection Control Elements
- Module 3: Equipment Reprocessing
- Module 4: Patient Tracers
- Module 5: Special Care Environments

Each module contains several sections, each of which describes the elements to be assessed. The modules of most direct relevance to the high-level disinfection and sterilization of medical devices are Modules 1, 2, and 3. Table 5 summarizes the elements specified in those modules. The table is not all-inclusive of those elements, but instead focuses on those most directly applicable to HLD and sterilization. Annex H provides the document in full.

In summary, CMS surveyors want to see complete compliance with the CoP and to ensure that healthcare organizations are conforming to all of the elements to be assessed during the survey. Responsibility for HLD and sterilization goes beyond the SPD and OR. Cleaning, disinfection, packaging, sterilization, and sterile storage take place in many areas, which will also be assessed by CMS surveyors. Following AAMI and AORN standards and recommended practices, as well as the guidelines of the CDC and other organizations, and being aware of what the CMS is looking for will help reprocessing personnel prepare for an accreditation survey and, more importantly, improve patient care.

TABLE 5 CMS Draft Surveyor Worksheet on Infection Control:²² Summary of Modules 1, 2, and 3

Module 1: Infection Control/Prevention Program

• Section 1.A Infection Control/Prevention Program and Resources

- 1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).
- 1.A.2 The hospital has evidence that demonstrates the Infection Control Officer(s) is qualified and maintain(s) qualifications through education, training, experience or certification related to infection control consistent with hospital policy.
- 1.A.3 The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law.*

• Section 1.D Personnel Education System/Infection Control Training

- 1.D.1 Healthcare personnel receive job-specific training on hospital infection control practices, policies, and procedures upon hire and at regular intervals.
- 1.D.2 The hospital infection control system trains healthcare personnel that are in contact with bloodborne pathogens on the bloodborne pathogen standards upon hire and when problems are identified.
- 1.D.10 Healthcare personnel competency and compliance with job-specific infection prevention policies and procedures are ensured through routine training and when problems are identified by the Infection Control Officer.†

Module 2: General Infection Control Elements

• Section 2.C Personal Protective Equipment/Standard Precautions

- 2.C.1 Supplies for adherence to Standard and Transmission-based Precautions (e.g., gloves, gowns, mouth, eye, nose, and face protection) are available and located near point of use.
- 2.C.2 HCP [healthcare personnel] wear gloves for procedures/activities where contact with blood, body fluids, mucous membranes, or non-intact skin is anticipated.‡
- 2.C.4 Gowns are worn to prevent contamination of skin and clothing during procedures/activities where contact with blood, body fluids, secretions, or excretions is anticipated.
- 2.C.6 Appropriate mouth, nose, eye protection is worn for aerosol-generating procedures and/or procedure/activities that are likely to general splashes or sprays of blood or body fluids.§

* Such guidelines would include the standards, recommended practice, and guidelines published by such organizations as AAMI, APIC, AORN, CDC, and SGNA.

† ANSI/AAMI ST79³ provides specific recommendations regarding the training and qualifications of reprocessing personnel.

‡ For personnel working in the decontamination area, PPE should include heavy-duty utility gloves and a liquid-resistant covering with sleeves (e.g., a backless gown, jumpsuit, or surgical gown).³

§ PPE should include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles.³



TABLE 5 CMS Draft Surveyor Worksheet on Infection Control:²² Summary of Modules 1, 2, and 3 (continued)

Module 3: Equipment Processing**

• Section 3.A Reprocessing of Semi-Critical Equipment††

- 3.A.1 All reusable semi-critical items receive at least high-level disinfection.
- 3.A.3 Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle.
- 3.A.4 Items are thoroughly pre-cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection. Note: For lumened instruments (e.g., endoscopes), pre-cleaning must include all device channels and lumens with cleaning brushes appropriate for size of instrument channel or port.
- 3.A.5 Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).
- 3.A.6 Cleaning brushes are disposable or cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after each use.
- 3.A.7 For chemicals used in high-level disinfection, manufacturer's instructions are followed for preparation, testing for appropriate concentration, replacement (e.g., prior to expiration or loss of efficacy).
- 3.A.8 If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected.
- 3.A.9 Devices are disinfected for the appropriate length of time as specified by manufacturer's instructions.
- 3.A.10 Devices are disinfected at the appropriate temperature as specified by manufacturer's instructions
- 3.A.11 After high-level disinfection, devices are rinsed with sterile water, filtered water, or tap water followed by a rinse with 70% - 90% ethyl or isopropyl alcohol.
- 3.A.12 Devices are dried thoroughly prior to reuse. Note: For lumened instruments (e.g., endoscopes) this includes flushing channels with alcohol and forcing air through the channels.
- 3.A.13 Routine maintenance procedures for high-level disinfection equipment conform to manufacturer's instructions; confirm maintenance records are available.
- 3.A.14 After high-level disinfection, devices are stored in a manner to protect from damage or contamination. (Note: Endoscopes must be hung in a vertical position.)
- 3.A.15 The facility has a system in place to identify which instrument (e.g., endoscope) was used on a patient via a log for each procedure.

** The CMS will be holding facilities accountable for accomplishing HLD and sterilization of reusable medical devices in a manner consistent with the facility's infection control policies and procedures. The policies and procedures should specifically address what to do when there are discrepancies between the medical device manufacturer's IFU and the reprocessor/sterilizer manufacturer's IFU.

†† High-level disinfection will be a major focus for CMS surveyors. According to the Spaulding classification system, any items that come in contact with non-intact skin or mucous membranes are considered semicritical and should receive at least high-level disinfection.²³ See 3.A.1 of the CMS surveyor worksheet.

TABLE 5 CMS Draft Surveyor Worksheet on Infection Control:²² Summary of Modules 1, 2, and 3 (continued)

• **Section 3.B Reprocessing of Critical Equipment; Sterilization of Reusable Instruments and Devices^{‡‡}**

- 3.B.1 Items are thoroughly pre-cleaned according to manufacturers' instructions and visually inspected for residual soil prior to sterilization. Note: For lumened instruments, pre-cleaning must include all device channels and lumens with cleaning brushes appropriate for size of instrument channel or port.
- 3.B.3 Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).
- 3.B.4 Cleaning brushes are disposable or cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after each use.
- 3.B.5 After pre-cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, hinged instruments are open, and instruments are disassembled if indicated by the manufacturer).
- 3.B.6 A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.
- 3.B.7 A biological indicator is used at least weekly for each sterilizer and with every load containing implantable devices.
- 3.B.8 For dynamic air removal-type sterilizers, a Bowie-Dick test is performed each day the sterilizer is used to verify efficacy of air removal.
- 3.B.9 Sterile packs are labeled with the sterilizer used, the cycle or load number, and the date of sterilization.
- 3.B.10 Logs for each sterilizer cycle are current and include results from each load.
- 3.B.11 Routine maintenance for sterilization equipment is performed according to manufacturer's instructions (confirm maintenance records are available).
- 3.B.12 After sterilization, medical devices and instruments are stored so that sterility is not compromised.
- 3.B.13 Sterile packages are inspected for integrity and compromised packages are reprocessed prior to use.
- 3.B.14 If immediate-use steam sterilization is performed, the following criteria are met:
 - ◆ The item being sterilized is thoroughly cleaned prior to placing it in the sterilizer container (that is FDA cleared for use with the cycle) or tray.
 - ◆ The sterilizer cycle being used is one that is approved by both the instrument and sterilizer manufacturer.
 - ◆ The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic) that are approved for the cycle being used.
 - ◆ The facility maintains a sufficient volume of instruments to meet the surgical volume and permit time to complete all steps of reprocessing.
- 3.B.15 Instruments that are subject to immediate-use sterilization procedures are used immediately and handled in a manner to prevent contamination during transport from the sterilizer to the patient.
- 3.B.16 HCP respond (i.e., recall of device and risk assessment) according to facility policies and procedures in the event of a reprocessing error/failure that could result in the transmission of infectious disease.

^{‡‡} The CMS worksheet clearly indicates that if any of the elements in Section 3.B are not met, the healthcare facility should receive a 42 CFR 482.42(a)(1) citing.

TABLE 5 CMS Draft Surveyor Worksheet on Infection Control:²² Summary of Modules 1, 2, and 3 (continued)

- Section 3.C Single-Use Devices (SUDs)⁵⁵

Single-use devices are used in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:

- 3.C.1 Single-use devices are discarded after use and not used for more than one patient.
- 3.C.2 If the hospital elects to reuse single-use devices, these devices are reprocessed by an entity or a third-party reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The hospital must have documentation from the third-party reprocessor confirming this is the case.

⁵⁵ The CMS worksheet states that if the answer is “no” to any of the assessed elements in Section 3.C, surveyors should cite 42 CFR 484.17(a).



CHAPTER 5

Other Accrediting Organizations

Overview

Numerous organizations provide accreditation services, either for an independent accreditation or for purposes of complying with CMS standards. The various organizations differ in their requirements. For many healthcare facilities, cost might be a factor in whether to seek accreditation and by whom. In some cases, for various internal reasons, healthcare facilities might seek accreditation from more than one organization. However, CMS and state departments of health only require accreditation from one accreditation organization.

DNV Healthcare

In September 2008, CMS approved DNV Healthcare (a subsidiary of Det Norske Veritas, a private, nonprofit, Norway-based foundation) as an accrediting organization for healthcare facilities that wish to be reimbursed by Medicare. The other approved organizations are listed in Chapter 4.

DNV's mission is to "protect life, property, and the environment" by recommending and setting standards for many industries. DNV's accreditation program for healthcare facilities is called National Integrated Accreditation for Healthcare Organizations (NIAHO). Currently, DNV standards are applicable only to hospitals; however, accreditation programs for other types of healthcare facilities are being planned. So far, more than 120 U.S. hospitals have either achieved DNV accreditation or are in the process of doing so.²⁴

International Organization for Standardization (ISO) standards are the basis for most of DNV's work, particularly those that pertain to quality systems. A major reason why some hospitals choose to obtain DNV accreditation is the option to achieve ISO 9001²⁵ certification.²⁴

The DNV performs annual unannounced accreditation surveys. The size and complexity of the hospital determine the number of surveys and the number of the survey days. Survey teams consist of a nurse or physician and a physical environment specialist. NIAHO accreditation standards and related literature are available free at: www.dnv.com/industry/healthcare. The standards, which are linked to the CMS Conditions of Participation and to ISO 9001, change only when the Conditions of Participation or ISO 9001 requirements change.²⁴

American Association for Accreditation Of Ambulatory Surgery Facilities

The American Association for Accreditation of Ambulatory Surgery Facilities, Inc. was established in 1980 to develop an accreditation program to standardize and improve the quality of medical and surgical care in ambulatory surgery facilities while assuring the public of high standards for patient care and safety in an accredited facility.²⁶ AAAASF accreditation surveys are conducted by physicians and nurses to confirm that ambulatory surgery facilities meet nationally recognized safety standards. AAAASF accreditation is intended for ambulatory surgery facilities in which therapeutic and diagnostic procedures are carried out by gastroenterologists, urologists, gynecologists, and pain management specialists. These procedures include both minimally invasive procedures and minor surgical procedures (e.g., intraoral maxillofacial procedures and minor urological procedures such as circumcisions and vasectomies). AAAASF regularly revises and updates its requirements for patient safety and quality of care.

AAAASF's *Procedural Standards and Checklist for Accreditation of Ambulatory Facilities*²⁷ can be found at: www.aaaasf.org. Procedures pertaining to sterilization are excerpted in Annex I.

Accreditation Association For Ambulatory Health Care

The Accreditation Association for Ambulatory Health Care is a private, independent, nonprofit organization that was established in 1979; it has accredited more than 5,200 healthcare facilities.²⁸ The AAAHC accreditation program applies specifically to ambulatory healthcare organizations, including ambulatory healthcare clinics, ambulatory surgery centers, birthing centers, university health centers, dental group practices, occupational health centers, office-based surgery centers and practices, pain management centers, urgent-care centers, and others. AAAHC has special programs for specific types of ambulatory care facilities.

Accreditation standards are provided in the *AAAHC Accreditation Handbook for Ambulatory Health Care*²⁹ and the *AAAHC Accreditation Handbook including Medicare Requirements for Ambulatory Surgery Centers (ASCs)*.³⁰ These handbooks apply to surveys applied for as of Jan. 1, 2014.

Some of the changes for 2014, vs. the 2013 edition, include the consolidation or elimination of some chapters, the revision or movement of some standards, and the addition of several new standards. Chapter 7, "Infection Prevention and Control and Safety," includes a new standard requiring that medical staff members, health practitioners, employees, and others receive infection prevention education and training. Chapter 10, "Surgical and Related Services," includes a new standard on minimizing fire risks. The specific revisions reflected in the 2014 *Accreditation Handbook for Ambulatory Health Care* can be found at the AAAHC website.³¹

Information on obtaining the accreditation standards, a list of frequently asked questions, standards updates, information on available webinars, and the survey application can be found at: www.aaahc.org.

Accreditation Commission for Health Care

The Accreditation Commission for Health Care accredits home care agencies and associated providers, such as:

- Infusion nursing services
- Hospices
- Sleep laboratories and home testing services
- Home/durable medical equipment suppliers (DMEPOS)
- Clinical respiratory care services
- Medical supply providers
- Suppliers of rehabilitation and assistive technology (e.g., wheelchairs)
- Prosthesis fitter services
- Infusion pharmacies
- Ambulatory infusion centers
- Specialty pharmacies
- Private-duty home healthcare services

Information on applying for accreditation and obtaining the ACHC accreditation standards can be found at: www.achc.org.

American Osteopathic Association/ Healthcare Facilities Accreditation Program

The American Osteopathic Association (AOA) is the only accrediting agency for osteopathic medical colleges. It also accredits a variety of types of healthcare facilities. The AOA's accreditation services are provided by its Healthcare Facilities Accreditation Program (HFAP), which conducts surveys involving data analysis, direct observation, interviews, record reviews, and evidence-based guidelines. Areas assessed during HFAP surveys include:

- Clinical and nonclinical areas
- Facility operations and maintenance
- Facility personnel, including nonclinical staff
- Governance
- Medical staff
- Policies and procedures
- Quality assessment and performance improvement

The accreditation process typically takes at least six months from the time of application.

Accreditation manuals are available for acute-care hospitals, critical-access hospitals, ambulatory surgical centers, ambulatory care and office-based surgery centers, primary stroke centers, behavioral and mental health facilities, and clinical laboratories. Information on obtaining these materials and on applying for accreditation can be found at: www.hfap.org.

Community Health Accreditation Program

The Community Health Accreditation Program was created in 1965 and was the first accrediting body for community-based healthcare organizations in the United States. It was granted deeming authority by CMS in 1992 for home health services, in 1999 for hospices, and in 2006 for home medical equipment services. CHAP accredits the following programs and services:

- Home health services
- Hospices
- Home medical equipment providers
- Pharmacies
- Private-duty home health services
- Infusion therapy nursing
- Public health services
- Community nursing centers
- Supplemental staffing services

Further information on CHAP's accreditation program and *Standards of Excellence* is provided at: www.chapinc.org.

State Departments of Health

All states have healthcare licensing programs. Certification from an accreditation agency is a condition for licensing. In general, state departments of health do not directly certify or accredit healthcare facilities, but most do inspect newly constructed or renovated facilities. They also handle complaints from the public and respond to communicable disease outbreaks. It is important to know the licensure requirements for the state in which the healthcare facility is located.



CHAPTER 6

Standards and Evidence-Based Guidelines

Overview

During a survey, accreditation agencies are looking for conformance to best practices and adherence to the facility's written policies and procedures. Many nationally recognized standards and recommended practices are available to healthcare facilities seeking guidance on writing policies and procedures. To obtain accreditation, healthcare facilities are expected to know, understand, and follow the most current published standards, recommended practices, and guidelines published by government agencies such as CDC and by professional organizations such as AAMI, AORN, the Association for Professionals in Infection Control and Epidemiology (APIC), the American Society for Gastrointestinal Endoscopy (ASGE), the Society for Healthcare Epidemiology of America (SHEA), and the Society of Gastroenterology Nurses and Associates (SGNA). Best practices are established on the basis of sound principles, scientific data, and the opinions of experts in the field. Following best practices is essential to the safety and quality of patient care. There are many published sources of best practices related to the sterile processing of surgical instruments and other medical devices in healthcare settings. Information available from AAMI, AORN, APIC, ASGE, SHEA, and SGNA, as well as the CDC, is summarized in this chapter.

Association for the Advancement of Medical Instrumentation (AAMI)

The Association for the Advancement of Medical Instrumentation (AAMI) is a professional organization whose membership includes healthcare professionals, representatives of medical device and sterilizer manufacturers, researchers, and regulatory officials. Standards, recommended practices, and technical information reports are developed according to consensus procedures by technical committees consisting of approximately equal numbers of healthcare experts, manufacturers' representatives, and regulatory and general-interest experts. AAMI is the primary organization in the United States that develops American National Standards related to sterile processing and that coordinates U.S. participation in international standards. Recently, AAMI has been working closely with the Joint Commission to provide educational programs to both TJC surveyors (on what to look for during a survey with respect to sterile processing) and healthcare professionals (on what to expect from a survey and how to prepare for it).

Table 6 lists the standards, recommended practices, and other technical documents that will be of most interest to sterile processing personnel.

AAMI’s American National Standard, ANSI/AAMI ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*,³ provides guidelines for activities pertaining to steam sterilization. However, it is relevant to all sterilization technologies and is widely referenced by professional organizations and government agencies. Like all AAMI standards and recommended practices, ANSI/AAMI ST79 is reviewed

and updated periodically to reflect new data and technological developments. All sterile processing, operating room, and infection prevention and control personnel should have access to the most recent edition of this document, which at the time of this writing is ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013.

Annex F highlights key provisions of ANSI/AAMI ST79 that relate to issues that accreditation surveyors might scrutinize. For each section of ANSI/AAMI ST79, pertinent TJC standards are referenced.

TABLE 6 **AAMI Standards, Recommended Practices, and Technical Information Reports Related to Sterile Processing**

DESIGNATION	TITLE
Recommended practices for sterile processing in healthcare facilities	
ANSI/AAMI ST79	<i>Comprehensive guide to steam sterilization and sterility assurance in health care facilities</i>
ANSI/AAMI ST41	<i>Ethylene oxide sterilization in health care facilities: Safety and effectiveness</i>
ANSI/AAMI ST58	<i>Chemical sterilization and high-level disinfection in health care facilities</i>
ANSI/AAMI ST65	<i>Processing of reusable surgical textiles for use in health care facilities</i>
ANSI/AAMI ST40	<i>Table-top dry heat (heated air) sterilization and sterility assurance</i>
ANSI/AAMI ST77	<i>Containment devices for reusable medical device sterilization*</i>
Standards for sterilization equipment intended for use in healthcare facilities*	
ANSI/AAMI ST8	<i>Hospital steam sterilizers</i>
ANSI/AAMI ST55	<i>Table-top steam sterilizers</i>
ANSI/AAMI ST24	<i>Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities</i>
ANSI/AAMI ST50	<i>Dry heat (heated air) sterilizers</i>
Technical information reports	
AAMI TIR12	<i>Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers*</i>
AAMI TIR30	<i>A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*</i>
AAMI TIR31	<i>Process challenge devices/test packs for use in health care facilities</i>
AAMI TIR34	<i>Water for the reprocessing of medical devices</i>

* Although these documents are primarily intended for medical device or sterilizer manufacturers, the information contained in them might be helpful to healthcare professionals.

Association of periOperative Registered Nurses (AORN)

“The Association of periOperative Registered Nurses (AORN) is the national association committed to improving patient safety in the surgical setting. AORN is the premier resource for perioperative nurses, advancing the profession and the professional with valuable guidance as well as networking and resource-sharing opportunities. AORN promotes safe patient care and is recognized as an authority for safe operating room practices and a definitive source for information and guiding principles that support day-to-day perioperative nursing practice.”³²

AORN recommended practices (RPs) are intended to illustrate best practices and to promote the safety of patients and healthcare workers. The RPs are based on principles of nursing science, microbiology, research, review of the scientific literature, and the opinions of knowledgeable experts. The RPs “are intended as achievable recommendations representing what is believed to be an optimal level of practice.”³³ Surgical and invasive procedure settings include operating rooms, ambulatory surgery centers, physicians’ offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery and other invasive procedures may be performed.

AORN recommended practices are reviewed and revised periodically. Currently, there are 32 RPs categorized into five sections:

- Aseptic practice
- Equipment and product safety
- Patient and worker safety
- Patient care
- Sterilization and disinfection

The section on sterilization and disinfection contains six RPs related to sterile processing:

• Recommended Practices for Cleaning, Handling, and Processing Anesthesia Equipment

Guidelines for cleaning, handling, processing, and disposal of anesthesia equipment and instrumentation, including the following:

- Sterilization or high-level disinfection of anesthesia equipment that comes in contact with mucous membranes
- Cleaning of anesthesia equipment that comes in contact with intact skin
- Use and disposal of single-use anesthesia equipment
- Testing of anesthesia equipment for performance and safety

- Cleaning of internal components of anesthesia machine breathing circuits
- Disposal of biohazardous waste
- Safety of personnel (e.g., practices to prevent sharps injuries)
- Consistency of procedures in all practice settings
- Policies and procedures

• Recommended Practices for High-Level Disinfection

Guidelines for achieving safe and effective high-level disinfection of reusable instruments and equipment, including the following:

- Categorization of items as critical, semicritical, or noncritical
- Cleaning and decontamination
- Pasteurization for thermal high-level disinfection
- Use of FDA-cleared chemical high-level disinfectants
- Protection of high-level-disinfected items from contamination before use
- Safety considerations for personnel
- Disposal of chemical disinfectants
- Education and competency assessment of personnel
- Documentation of high-level disinfection
- Policies and procedures
- Quality control

• Recommended Practices for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories

Guidelines on processing endoscopes and providing a safe environment for patients and healthcare workers, including the following:

- Manufacturers’ instructions
- Precleaning
- Transport to the decontamination area
- Leak testing
- Manual cleaning
- High-level disinfection or sterilization
- Rinsing, alcohol treatment, and drying
- Inspection
- Storage
- Decontamination and inspection of flexible endoscope accessories
- Physical separation of decontamination and clean areas



- PPE
- Education and competency assessment of personnel
- Documentation of cleaning and processing
- Policies and procedures
- Quality control
- **Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment**
Guidelines for decontaminating surgical instruments and powered equipment and preparing them for sterilization, including the following:
 - Prepurchase review of manufacturers' instructions
 - Examination, cleaning, and sterilization of new, repaired, and refurbished instruments according to the manufacturer's instructions, before use
 - Examination, cleaning, and sterilization of loaner instruments, according to the manufacturer's instructions, before use
 - Removal of gross soil during the surgical procedure
 - Timely cleaning and decontamination after use
 - Containment and transport of contaminated instruments
 - Physical separation of decontamination and clean areas
 - Water quality
 - Cleaning agents
 - Cleaning methods
 - Inspection for cleanliness and performance after decontamination
 - Packaging of cleaned surgical instruments
 - Decontamination, lubrication, assembly, sterilization, and testing of powered surgical instruments and attachments
 - Precautions to be taken when reprocessing ophthalmic surgical instruments
 - Decontamination and inspection of insulated electrosurgery instruments
 - Precautions to be taken when cleaning robotic instruments
 - Precautions to be taken to minimize the risk of transmission of prion diseases
 - Personnel safety (PPE, hepatitis B vaccination)
 - Education and competency assessment of personnel
 - Documentation
 - Policies and procedures
 - Quality control

- **Recommended Practices for Selection and Use of Packaging Systems for Sterilization**

Guidelines for the evaluation, selection, and use of packaging systems for items to be sterilized, including the following:

- Prepurchase evaluation of packaging systems
- Compatibility of packaging with the sterilization process
- Storage and processing of packaging materials
- Assembly, handling, and wrapping for aseptic presentation of package contents
- Paper–plastic pouches
- Rigid sterilization containers and other containment devices
- Labeling of packages
- Event-related sterility assurance
- Use of internal and external chemical indicators
- Quality management of packaging selection and use
- Education and competency assessment of personnel
- Policies and procedures

- **Recommended Practices for Sterilization**

Guidelines for sterilizing items to be used in the perioperative setting, including the following:

- Processing based on intended use of item
- Not reprocessing single-use devices except according to FDA guidelines
- Controlled environment for cleaning, decontamination, sterilization, and storage
- Manufacturers' instructions
- Inspection for cleanliness and functionality
- Packaging for sterilization
- Steam sterilization
- IUSS
- Ethylene oxide (EO) sterilization
- Low-temperature hydrogen peroxide gas plasma sterilization
- Low-temperature hydrogen peroxide vapor sterilization
- Ozone sterilization
- Dry heat sterilization
- Liquid chemical processing (peracetic acid)
- Loaned instrumentation
- Labeling and storage of sterilized items
- Transportation of sterile items



- Education and competency assessment of personnel
- Sterilization documentation
- Policies and procedures
- Quality assurance and performance improvement process

Association for Professionals in Infection Control And Epidemiology (APIC)

The mission of the Association for Professionals in Infection Control and Epidemiology is “to create a safer world through the prevention of infection. This is achieved by the provision of better care to promote better health at a lower cost.”³⁴ As a member of the Healthcare Infection Control Practices Advisory Committee, APIC has participated in the development of many CDC guidelines, including the *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*,²³ the *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*,³⁵ and the *Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Care*.³⁶

APIC’s guidelines include the following:

- **SHEA/ASHE Guideline: Infection Prevention and Control in the Long-Term Care Facility**,³⁷ which covers:
 - Epidemiology of infections in long-term care facilities
 - Urinary tract, respiratory, skin, and other infections common in long-term care facilities
 - Recommended infection control programs

A complete list of guidelines authored or co-authored by APIC can be found at: www.apic.org/Professional-practice/Scientific-guidelines³⁸ and www.apic.org/Professional-Practice/Implementation-guides.³⁹

American Society for Gastrointestinal Endoscopy (ASGE)

The American Society for Gastrointestinal Endoscopy is “dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE . . . promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.”⁴⁰

In 2003, ASGE and the Society for Healthcare Epidemiology of America jointly published a *Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes*. This guideline was endorsed by numerous professional associations. It was updated in 2011

and was endorsed by, in addition to ASGE and SHEA, the Accreditation Association for Ambulatory Health Care, the American Gastroenterological Association, the American College of Gastroenterology, the American Society of Colon and Rectal Surgeons, AORN, APIC, the Society of American Gastrointestinal Endoscopic Surgeons, and TJC.

- **Multisociety Guideline on Reprocessing of Flexible Gastrointestinal Endoscopes: 2011**,⁴¹ which covers the following:

- Levels of disinfection in relation to the Spaulding classification of medical devices
- Pathogen transmission
- Current level of compliance with guidelines on reprocessing flexible gastrointestinal endoscopes
- Issues requiring further study
- Specific recommendations on reprocessing flexible gastrointestinal endoscopes
 - ◆ Personnel training
 - ◆ Precleaning at the point of use
 - ◆ Transport of soiled endoscopes to the decontamination area
 - ◆ Pressure/leak testing
 - ◆ Cleaning procedures
 - ◆ Cleaning implements
 - ◆ Cleaning of reusable endoscopic accessories
 - ◆ Ultrasonic cleaning of reusable endoscopic accessories and endoscope components
 - ◆ Need for at least high-level disinfection
 - ◆ High-level disinfectants and automated high-level disinfection equipment
 - ◆ Exposure time and temperature for high-level disinfection
 - ◆ Compatibility of endoscopes with high-level disinfection
 - ◆ New high-level disinfectants, FDA clearance, and the scientific literature
 - ◆ Manual high-level disinfection
 - ◆ Automated endoscope reprocessors (AERs)
 - ◆ Rinsing and drying
 - ◆ Visual inspection
 - ◆ Storage
 - ◆ High-level disinfection or sterilization of water bottles used for cleaning endoscope lenses and irrigation during procedures

- ◆ Record-keeping for endoscopic procedures
- ◆ Routine testing of minimum effective concentration of high-level disinfectants
- ◆ Reuse life
- ◆ Facility design
- ◆ Device-specific processing instructions
- ◆ Personnel competency
- ◆ Hazard communication to personnel
- ◆ PPE
- ◆ Identification of when and where an endoscope has been reprocessed
- ◆ Routine microbiological testing of endoscopes
- ◆ Reprocessing of nonendoscopic devices, accessories, and attachments
- ◆ Infection prevention practices for aseptic administration of medications
- ◆ Investigation and reporting of endoscopy-related infections

Society for Healthcare Epidemiology of America (SHEA)

The Society for Healthcare Epidemiology of America's "mission is to prevent and control infections in healthcare settings. The society is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost-of-care linked to healthcare-associated infections."⁴²

Among the guidelines published by SHEA is the following:

- **Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments,**⁴³ which covers the following:
 - Epidemiology of the Creutzfeldt-Jakob disease (CJD) prion
 - Transmission of CJD via medical devices
 - Inactivation of the CJD prion
 - Decontamination, disinfection, and sterilization of prion-contaminated medical instruments
 - Standard precautions to prevent transmission from prion-contaminated instruments
 - General infection prevention precautions
 - Recommendations for processing CJD-contaminated patient care equipment and environmental surfaces

In 2003, SHEA and ASGE jointly published a *Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes*. This guideline was endorsed by numerous professional associations. It was updated in 2011⁴¹ and was endorsed by, in addition to ASGE and SHEA, the Accreditation Association for Ambulatory Health Care, the American Gastroenterological Association, the American College of Gastroenterology, the American Society of Colon and Rectal Surgeons, AORN, APIC, the Society of American Gastrointestinal Endoscopic Surgeons, and TJC. Key provisions of the guideline are summarized in the preceding section.

Society of Gastroenterology Nurses and Associates (SGNA)

"The Society of Gastroenterology Nurses and Associates is a professional organization of nurses and associates dedicated to the safe and effective practice of gastroenterology and endoscopy nursing. SGNA carries out its mission by advancing the science and practice of gastroenterology and endoscopy nursing through education, research, advocacy, and collaboration, and by promoting the professional development of its members in an atmosphere of mutual support."⁴⁴

SGNA has developed several standards and practice guidelines that are periodically reviewed and revised. These documents are available for free download at the SGNA web site.⁴⁵ The two SGNA standards and practice guidelines most directly related to sterile processing are the following:

- **Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes,**⁴⁶ which covers the following:
 - General principles common to the use of all high-level disinfectants
 - ◆ Medical device classification system (critical, semicritical, noncritical)
 - ◆ Product safety
 - ◆ General characteristics
 - ◆ Biofilm
 - ◆ Susceptibility of resistant organisms
 - ◆ Determination of minimum effective concentration (MEC)
 - ◆ Personal protective equipment (PPE)
 - ◆ Material compatibility
 - ◆ Manual cleaning
 - ◆ Final rinse, alcohol purge, storage

- ◆ High-level disinfectant and sterilant properties and handling recommendations
- Properties of and handling recommendations for high-level disinfectants and liquid chemical sterilants
 - ◆ Glutaraldehyde
 - ◆ 0.55% Ortho-phthalaldehyde
 - ◆ 0.2% Peracetic acid
 - ◆ 7.5% Hydrogen peroxide
 - ◆ 0.08% Peracetic acid–1% hydrogen peroxide
- Compatibility of high-level disinfectants with endoscopes
- FDA-cleared sterilants and high-level disinfectants
- List of various liquid chemical sterilants and disinfectants used to reprocess flexible gastrointestinal endoscopes in the United States
- ***Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes***,⁴⁷ which covers the following:
 - Definitions
 - Introduction
 - Personnel
 - Education and training
 - Quality assurance
 - Procedure rooms
 - Reprocessing rooms
 - Accessories
 - Infection control measures
 - Spill containment plan
 - Endoscope reprocessing protocol
 - ◆ Precleaning
 - ◆ Leak testing
 - ◆ Manual cleaning
 - ◆ Rinse after manual cleaning
 - ◆ High-level disinfection
 - Manual high-level disinfection
 - Automated reprocessing
 - ◆ Rinse after manual disinfection
 - ◆ Drying
 - ◆ Storage

Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention is a government agency charged with “collaborating to create the expertise, information, and tools that people and communities need to protect their health—through health promotion, prevention of disease, injury, and disability, and preparedness for new health threats.”⁴⁸ The agency develops evidence-based guidelines on many healthcare-related topics, including sterile processing. Although compliance with CDC guidelines is not mandatory, the guidelines are nationally recognized and are referenced by accreditation and professional organizations in standards and recommended practices. In its *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*, CDC provided “evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment.”²³ More than 1,000 scientific papers are cited in the 2008 guideline, which supersedes the *CDC Guideline for Handwashing and Environmental Control, 1985*.⁴⁹ Like the original guideline, the 2008 guideline covers cleaning methods as well as disinfection and sterilization methods. New topics addressed in the 2008 guideline include the following:

- Inactivation of antibiotic-resistant bacteria, bioterrorist agents, emerging pathogens, and bloodborne pathogens
- Toxicological, environmental, and occupational concerns associated with disinfection and sterilization practices
- Disinfection of patient care equipment used in ambulatory settings and home care
- New sterilization processes (e.g., hydrogen peroxide gas plasma, liquid peracetic acid)
- Disinfection of complex medical devices (e.g., endoscopes)

Commonly used sterilization methods covered in the guideline include steam sterilization, ethylene oxide sterilization, hydrogen peroxide gas plasma sterilization, peracetic acid sterilization, and dry heat sterilization. Sterilization methods that have not yet been cleared by FDA for use in healthcare facilities are also briefly addressed.

Although the 2008 guideline on disinfection and sterilization is of most direct relevance to sterile processing personnel, other CDC guidelines referenced in TJC surveyor training include the following:

- *Guideline for Prevention of Catheter-Associated Urinary Tract Infections, 2009*⁵⁰

- *Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006*⁵¹
- *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*⁵²
- *Influenza Vaccination of Health-Care Personnel*⁵³
- *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005*⁵⁴
- *Guidelines for Preventing Health-Care-Associated Pneumonia, 2003*⁵⁵
- *Guidelines for the Prevention of Intravascular Catheter-Related Infections*⁵⁶
- *Guideline for Hand Hygiene in Health-Care Settings*⁵⁷
- *Guideline for Infection Control in Health Care Personnel, 1998*⁵⁸
- *Guideline for Prevention of Surgical Site Infections, 1999*⁵⁹
- *Immunization of Health-Care Workers*⁶⁰
- *Guidelines for Environmental Infection Control in Health-Care Facilities*⁶¹

In July 2011, the CDC issued a document entitled *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*,³⁵ and a companion checklist, *Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Care*.³⁶

In these new documents, the CDC states that infection prevention programs should extend beyond OSHA bloodborne pathogen training and that facilities should ensure that at least one individual with training in infection prevention is employed by or regularly available to the facility. The infection preventionist should be involved in the development and ongoing refinement of infection prevention policies that are based on regulations, standards, or evidence-based guidelines. The policies should be tailored to the facility and reassessed on a regular basis (e.g., annually), taking into consideration the types of services provided by the facility and the patient population served by the facility. For example, an ASC that performs on-site sterilization of surgical equipment would be expected to have more detailed policies regarding equipment reprocessing than would a substance abuse clinic.

The CDC makes several key recommendations regarding the cleaning, disinfection, and sterilization of medical equipment in ambulatory care settings:³⁵

- Facilities should ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient.
- Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer's instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.
- Assign responsibilities for reprocessing of medical equipment to healthcare personnel with appropriate training.
 - Maintain copies of the manufacturer's instructions for reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed.
 - Observe procedures to document competencies of healthcare personnel responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly).
- Ensure that healthcare personnel have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment.

CHAPTER 7

The Proper Preparation

Overview

Successful accreditation surveys require proper preparation. Preparing for accreditation and certification is an ongoing process. The Joint Commission, CMS, and other accreditation organizations now perform unannounced surveys. Consequently, it is extremely important for healthcare facilities to be in a constant state of accreditation readiness in order to excel in providing safe and effective patient care and achieving accreditation.

Which Accreditation Organization?

The administration of the healthcare facility will have selected the organization from which accreditation will be sought. The choice of accreditation organization depends on several factors, including the size of the facility and the healthcare services it provides.

Accreditation Preparation Committee

Preparing for an accrediting agency survey as it relates to the reprocessing of surgical instruments and other medical devices in healthcare settings is no small task. Many of the activities that affect reprocessing take place in areas separate from the location where decontamination and sterilization are actually carried out. The delivery of sterile healthcare products for use in patient care depends not only on the efficacy of the sterilization process itself but also on the following factors:³

- Efficient facility design
- Proper training of personnel
- Good infection prevention and control practices designed to prevent healthcare-associated infections
- Effective quality control and process improvement systems that encompass all aspects of device reprocessing, from point of use through sterilization to reuse
- Appropriate documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used

A diversified accreditation committee should be appointed to examine the specific issues associated with reprocessing. The accreditation committee should include, but not be limited to, sterile processing, operating room, gastrointestinal (GI) laboratory, infection prevention and control, clinical/biomedical engineering, endoscopy, risk management, quality, safety, education, administration, facilities engineering, and materials management representatives.

Accreditation Documents

The accreditation preparation committee should gather the appropriate documents or standards from the chosen accreditation organization, particularly, of course, those that relate specifically to sterile processing. Annexes A, B, C, G, H, and I list pertinent sterile processing standards and other requirements from TJC, CMS, and AAAASF. In an earlier chapter, contact information for other accreditation organizations is provided. However, the complete accreditation materials from the chosen accreditation organization should be reviewed in detail.

It is important for the healthcare facility to stay up-to-date on the accreditation requirements of the chosen accreditation organization every year. “If you buy the new book every year, even if it’s not an accreditation year for you, you won’t have to do as much work to go through your survey because you’ve done the work every year. If, [instead], you take a break on non-accreditation years, you’re going to have to play catch up and do a lot more work.”⁶²

Important Actions to Take

The accreditation preparation committee should also ensure that job descriptions, evidence of education and training, and competencies are up-to-date, documented, and available. The job description and competencies should match the assigned duties of each staff member.

Up-to-date manufacturers’ IFU should be on file for the sterilizer equipment, packaging (containers, wrappers, and peel-packs), cleaning and disinfecting chemicals, and all monitoring devices (physical, chemical, and biological). The committee should ensure that current manufacturers’ IFUs are readily available to all staff (including decontamination area staff), either electronically or as paper documents.

Relevant Professional Standards and Recommended Practices

The accreditation preparation committee should also gather and review the latest editions of relevant standards, recommended practices, and guidelines from such organizations as AAMI, AORN, APIC, ASGE, SHEA, SGNA, and CDC (see Chapter 6). Pertinent local, state, and federal regulations should also be reviewed.

Policies and Procedures

A key aspect of successful accreditation is demonstrating compliance with the facility’s own policies and procedures. One of the first and most important steps that the accreditation committee should take in preparing for a survey is to assess the facility’s existing policies and procedures and ensure that they reflect the most current regulations and professional standards and recommended practices related to sterile processing. It might be necessary to revise or update the facility’s sterile processing policies and procedures to reflect the most current standards of care.

The policies and procedures governing sterile processing should be standardized within the facility and should be developed in consultation with the managers of areas that use sterile medical devices and with appropriate committees or functional groups within the facility (e.g., infection prevention and control, safety, hazardous materials, risk management). In addition, the support of the facility’s administration is vital.

Referencing policies and procedures to specific current standards, recommended practices, and guidelines from AAMI, AORN, APIC, ASGE, SHEA, SGNA, CDC, and other organizations will be beneficial and might well be checked by accreditation surveyors, because using evidence-based guidelines is part of TJC’s leadership standard (see Annexes A, B, and C). Important aspects of sterile processing that should be addressed in written policies and procedures include, but are not limited to, the following:

- Facility design
 - Work area design and functional work flow
 - Physical plant (e.g., steam supply, electrical utilities, eyewash stations)
 - Housekeeping
- Personnel
 - Qualifications
 - Training and continuing education
 - Health and personal hygiene



- Dress code, PPE
- Standard/transmission-based precautions
- Receiving
 - Purchased or loaner items
 - Sterile items issued but not used
- Handling, collection, and transport of contaminated items
 - Care and handling of contaminated reusable items at point of use
 - Containment
 - Transport
- Decontamination
 - Manufacturer’s instructions for use
 - Presoaking
 - Disassembly
 - Cleaning and rinsing
 - Disinfection procedures to ensure devices are safe to handle
- Maintenance and repair of medical devices
 - In-house program (scheduled and corrective maintenance)
 - Return of devices to manufacturer
 - Record-keeping
- Packaging
 - Package configuration
 - Labels
 - Closures
 - Paper–plastic pouches
 - Textile packs
 - Rigid sterilization containers and other containment devices
- Preparation and assembly of surgical instrumentation
 - Weight and density of sets
 - Inspection
 - Instrument placement
 - Tray liners
 - Containment devices
- Loading the sterilizer
- Sterilization parameters
 - Manufacturer’s instructions for use
 - Specialty/complex instruments
- Unloading the sterilizer
- Sterile storage
 - Event-related shelf life
 - Storage systems
- Handling and inspection of sterile packages
- Transport of sterile items
- Aseptic presentation
- Installation and maintenance of sterilizers
 - Instruction manuals
 - Routine care
 - Preventive maintenance
 - Repair
 - Record-keeping
- Quality control
 - Monitoring of mechanical cleaning equipment and manual cleaning
 - Product labeling and traceability (lot control, sterilization records, expiration dating)
 - Sterilization process monitoring devices (physical, chemical, biological monitors; process challenge devices)
 - Monitoring of implant and non-implant loads for load release
 - Routine sterilizer efficacy monitoring
 - Sterilizer qualification testing
 - Periodic product quality assurance testing
 - Product recalls
- Quality process improvement
 - Risk analysis
 - Implementation of product and process improvements
- Evaluation of new products

Performing Audits

Sterile processing plays a major role in patient safety, and its importance cannot be overestimated. The safe reprocessing of reusable instruments and equipment takes knowledgeable, responsible personnel with critical thinking skills and a workplace that facilitates effective and efficient processing.

Accrediting surveyors understand the roles and responsibilities of sterile processing personnel as those roles and responsibilities relate to safety. Surveys will increasingly focus on reprocessing, and surveyors will be looking for compliance with published standards and guidelines.

Audits reveal weaknesses that can be addressed before an accreditation survey uncovers them. Clinical practices and infection control guidelines continue to be developed as understanding of the risk factors for and strategies for prevention of infections increases. Technology is changing the way procedures are performed as well as how instruments, equipment, and supplies are reprocessed. The most current published professional recommendations for cleaning, disinfection, sterilization, sterile storage, environmental cleaning, facility design, and personnel considerations should be strictly followed; and adherence to policies and procedures should be closely monitored. Performing routine audits can help identify opportunities for specific quality process improvements and will help facilities stay in a state of readiness for unannounced surveys.

Examples of reprocessing audit tools for sterile processing, IUSS, and high-level disinfection are provided in Annexes J, K, and L, respectively. These tools can be used as facility guides for auditing reprocessing areas for best practices.

The Sterile Processing Best Practices Audit Tool is designed to follow sections of ANSI/AAMI ST79,³ including the following:

- Design considerations
- Personnel considerations
- Receiving, handling, collection, and transport of contaminated items
- Cleaning and other decontamination processes
- Packaging, preparation, and sterilization
- Installation, care, and maintenance of sterilizers
- Quality control
- Quality process improvement
- New product evaluation
- Policies and procedures

These audit tools can be used to perform a comprehensive audit. Doing a thorough audit might be time-consuming; therefore, facilities might want to consider auditing only specific sections at one time. However, a comprehensive audit of all sections should be completed routinely (e.g., annually) to ensure that the correct procedures and practices are being maintained.

Staff Knowledge and Education

Involving reprocessing staff in the accreditation preparation process helps ensure that they understand and follow current policies and procedures and they understand the reasons for changes and process improvement over time. Understanding the rationale behind changes improves acceptance and leads to

better compliance. Anyone involved in reprocessing should be knowledgeable of standardized practices and capable of exercising critical thinking and judgment.

Communication is key. Educating staff members and other invested parties (e.g., industry vendors) about policy changes and the rationale behind policy updates is essential for compliance. Communication should be in writing and ongoing to ensure that all personnel are conversant with current policies and procedures.

A well-informed staff is instrumental in achieving a successful audit. Surveyors see employees as the face of the facility. Having employees speak with surveyors and be open to suggestions and comments will leave a more positive impression on the surveyor. The natural instinct is to try and avoid surveyors, but staff should be encouraged not to walk away but instead to be available and to let the surveyors know that they take pride in what they do.

The healthcare facility leadership is responsible for ensuring that the staff has appropriate training, education, and competency and is provided with the necessary resources for effective and efficient reprocessing of surgical instrumentation.

Audits and Quality Improvement Opportunities

Reprocessing procedures should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with appropriate departments and integrated into the overall quality process in the healthcare facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, the healthcare facility policies and procedures for the handling of unfavorable or unplanned events, and on the type of process variable.³

A problem analysis should be completed for any problem relating to any aspect of surgical instrument processing that could pose a risk to personnel or patients. The problem analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.³ See also the next section, “Risk Analysis,” and Chapter 8.

Audits should be conducted to ensure that the most current policies, procedures, and guidelines are being followed. Performance measures that can be used for process improvement and auditing purposes are described in ANSI/AAMI ST79.³ Reprocessing technicians and OR staff should be involved in process audits. Action plans should be developed to address problems noted during an audit, and a follow-up audit should be scheduled to ensure that the problems have been addressed and that the correct processes are being maintained.