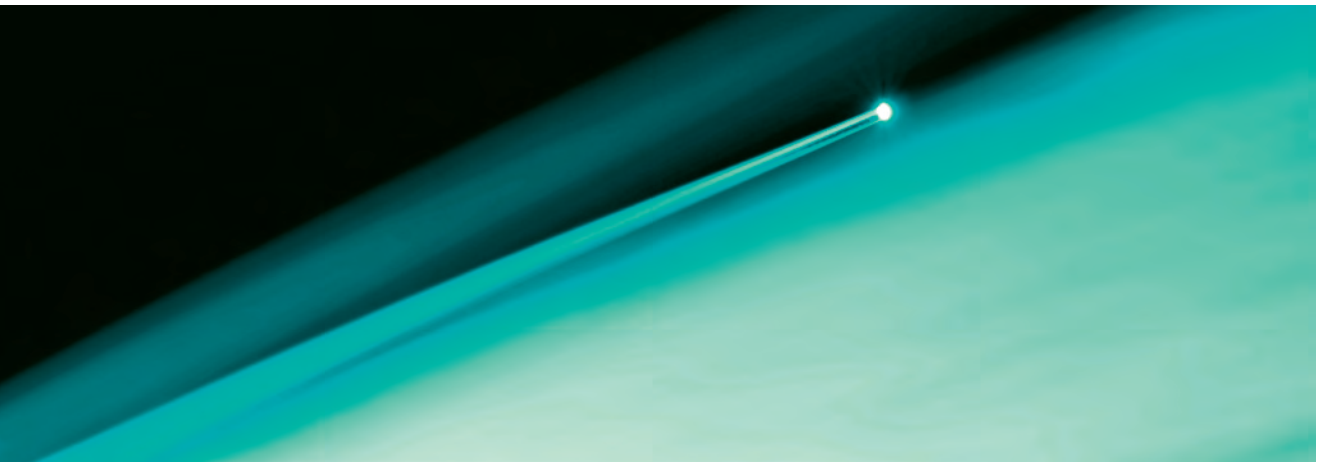
AAMI
Advancing Safety in Medical Technology

2nd Edition

Sterile Processing In Healthcare Facilities Preparing for Accreditation Surveys



Rose Seavey

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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,
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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 (AAAHC), 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 health care 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.

Sterile[3] Free from viable microorganisms.

Sterilization[3] Validated process used to render a product free from viable microorganisms.

Abbreviations

AAAASF American Association for Accreditation of Ambulatory Surgery Facilities

AAAHC 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*

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

CDC Centers for Disease Control and Prevention

CDS Cleaning, disinfection, and sterilization

CFR *Code of Federal Regulations*

CHAP Community Health Accreditation Program

CJD Creutzfeldt-Jakob disease

CMS Centers for Medicare & Medicaid Services

CoP Conditions of participation

CVO Credentials verification organization

DMEPOS Home/durable medical equipment suppliers

DNV DNV (Det Norske Veritas) Healthcare, an accrediting organization for health care facilities

EC Environment of care

EO Ethylene oxide

EP Element of performance

FDA U.S. Food and Drug Administration

FMEA Failure modes and effects analysis

FSA Focused standards assessment

HAI Healthcare-associated infection

HFAP Healthcare Facilities Accreditation Program

HFMEA Healthcare failure mode and effect analysis

HHA Home health agency

HLD High-level disinfection

IAHCSMM International Association of Healthcare Central Service Materiel Management

ICM Intracycle monitoring process

IFU Instructions for use

ISO International Organization for Standardization

IUSS Immediate-use steam sterilization

MEC Minimum effectiveness concentration

MOS Measure of success

MSDS Material safety data sheet

NFPA National Fire Protection Association

NIAHO National Integrated Accreditation for Healthcare Organizations

NIST National Institute of Standards and Technology

NPSG National Patient Safety Goal

OPA Ortho-Phthalaldehyde

OSHA Occupational Safety and Health Administration

PER Preliminary evidence report

PPE Personal protective equipment

PPR Periodic performance review

QC Quality Control

RCA Root cause analysis

RFI Requirements for improvement

RP Recommended practice

SGNA Society of Gastroenterology Nurses and Associates

SHEA Society for Healthcare Epidemiology of America

SPD Sterile Processing Department

SSI Surgical site infection

SUDS Single-use devices

TEE Transesophageal echocardiogram

TJC The Joint Commission

UP Universal Protocol

VA U.S. Veterans Administration

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.