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Sterile Processing in Healthcare Facilities

Preparing for Accreditation
Surveys, 3rd Edition

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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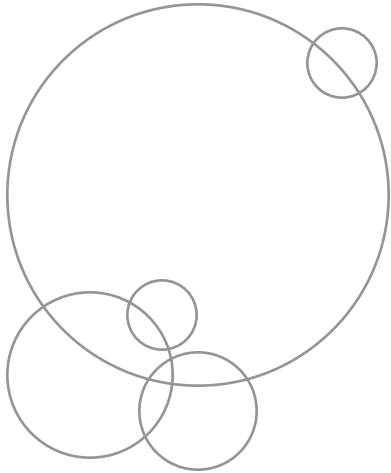


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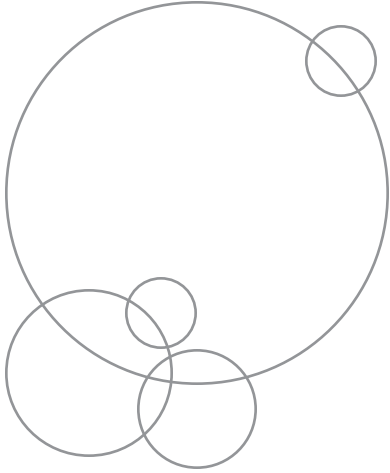
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Dedication

To all of my mentors who have helped me throughout my career: You have guided me in more ways than I can remember. Without your assistance, insight, and inspiration, this book would not have been possible. Many thanks to each and every one of you.

Acknowledgments

While creating the third edition of 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.

I would also like to acknowledge and thank my many OR, SPD, and IP colleagues and mentors who helped and guided me throughout my professional career. Your support and dedication has always helped guide me into doing the right thing for the safety of our patients and employees.

Thank you,

Rose Seavey, MBA, BS, RN, CNOR, CRCST, CSPDT

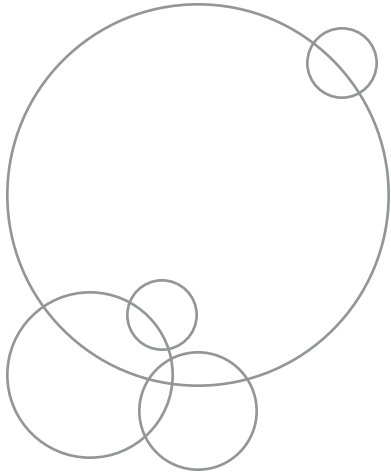
About the Author



Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT is the president/CEO of Seavey Healthcare Consulting, LLC, and formerly the director of the Sterile Processing Department at The Children's Hospital of Denver. Ms. Seavey served on the Association of periOperative Registered Nurses (AORN) Board of Directors from 2008–2010. She received AORN's award for Outstanding Achievement in Mentorship in 2012 and the Outstanding Achievement in Clinical Nurse Education in 2001.

In 2003, Rose served as president of the American Society of Healthcare Central Service Professionals (ASHCSP) and was awarded the National Educator of the Year award in 2002. Rose was selected as one of the Who's Who in Infection Prevention in 2006 by Infection Control Today. She also received the 2013 national IAHCSSM Award of Honor, the Industry Leadership Award from the Massachusetts chapter, and the Educator of the Year Award from the Golden West chapter.

Ms. Seavey sat on the AAMI National Nominating Committee for 2011–2014 and cochaired the AAMI Working Group for Hospital Steam Sterilizers from 2006–2013. She is a member of several AAMI working groups and has lectured nationally and internationally and authored numerous articles.

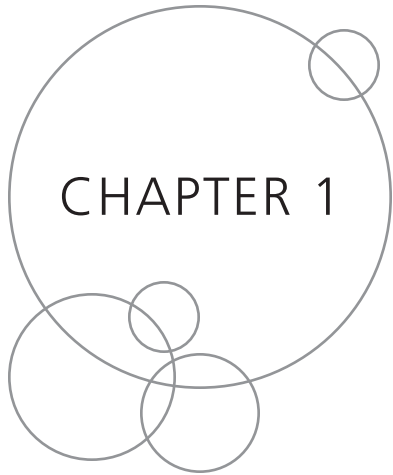


Foreword

The purpose of this guidance document is to help healthcare professionals prepare for an accrediting agency survey as it relates to the reprocessing of surgical instruments, endoscopes, and other reusable medical devices in any healthcare setting. 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 (AAAH), the Accreditation Commission for Health Care (ACHC), the Center for Improvement in Healthcare Quality (CIHQ), the Community Health Accreditation Partner (CHAP), The Compliance Team (TCT), DNV GL - Healthcare (DNV GL), the Healthcare Facilities Accreditation Program (HFAP), 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 healthcare 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 examples of sterile processing auditing tools. New to this third edition are best-practice audit tools for immediate-use steam sterilization (IUSS) and high-level disinfection (HLD), and an instrument integrity checklist. This edition has also been updated to reflect the 2017 revision of ANSI/AAMI ST79 and current TJC accreditation standards related to sterile processing. The TJC standards for critical access hospitals have been added, as well as the performance improvement (PI) standards and elements of performance (EPs) for all healthcare facilities covered here (hospitals, critical access hospitals, ambulatory care facilities, and office-based surgery facilities). TJC's new SAFER matrix scoring methodology is also discussed.



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, risk assessments, 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 conditions of participation (CoPs).

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 evidence-based 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). 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}