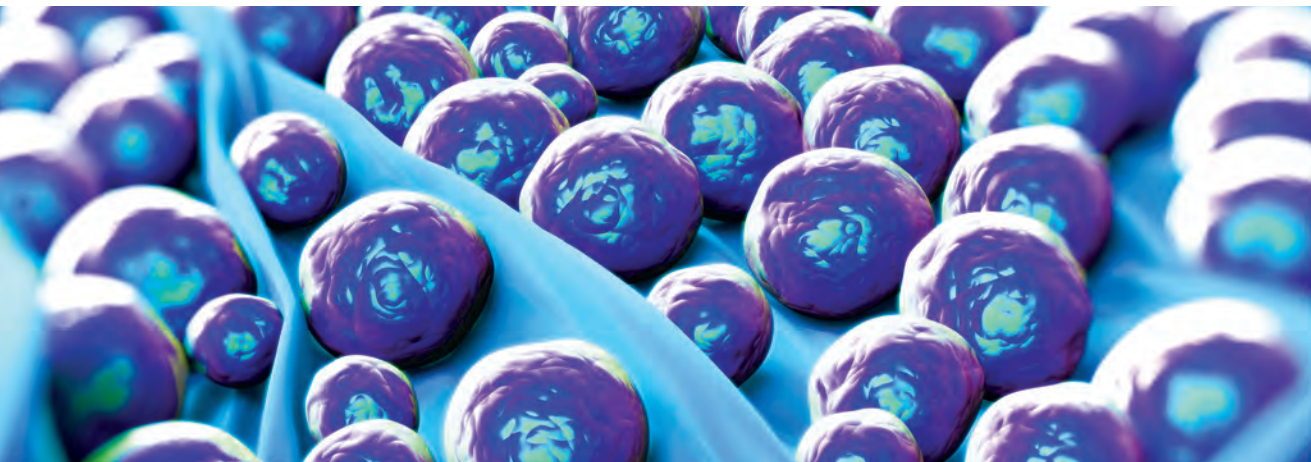




Basic Concepts in Sterilization Processes Verification, Validation, And Qualification



Donna Swenson

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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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Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

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Printed in the United States of America

ISBN 1-57020-521-3

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Foreword

Modern medicine as we know it would never have existed without the advent of disinfection and sterilization. Through the early 19th century, the inside of the living human body was the doctor's equivalent to those areas on old maps marked "Here there be dragons"—it was dangerous territory to be avoided whenever possible. Voluntary surgery was largely limited to minimally invasive procedures such as blood-letting, tooth extraction, and removing kidney stones by dilating the urethra. Invasive surgery's high rate of mortality, which resulted from both infections and the rudimentary nature of surgical technique, made such procedures a tool of last resort.

Medical pioneers like Louis Pasteur and Edward Jenner changed this. Not only did they establish the causal connection between microbes and infections, they created methods and technologies to control the former and thereby prevent the latter. With the introduction of these practices, the interior body cavity was no longer terra incognita for doctors. Physicians were able to surgically treat conditions previously considered death sentences; surgery became safer, medical knowledge flourished, and surgical technique advanced. Since the first successful appendectomy in 1884, surgery has progressed to the point where robots are now used to repair the heart, and what were formerly major surgeries have become outpatient procedures.

Key to this battle against surgical infections has been the role played by those who reprocess the medical instruments used in surgery. Since the invention of the autoclave in 1879, steam sterilization has been the primary choice for treating heat-resistant surgical instruments, like those made of metal or glass. Instruments that could not withstand the high temperatures or humidity of steam sterilization were treated using dry heat or by a variety of chemical sterilants or disinfectants. When devices were properly cleaned and disinfected or sterilized, post-surgical infections arising from device contamination were extraordinarily rare—and where post-surgical infections did occur, they could be easily treated using 20th century antibiotics.

This almost 150 years of unbroken success in fighting and preventing infections, however, is being challenged. The appearance of antibiotic-resistant bacteria, like methicillin-resistant *Staphylococcus aureus* and carbapenem-resistant *Enterobacteriaceae*, means that hospital-acquired infections can be more dangerous and harder to treat. The increased complexity of new medical instruments—such as endoscopes and those used in robot-assisted surgery—and the incorporation of delicate materials and sensitive electronics into devices, are making the work of reprocessing personnel similarly more complicated and demanding.

Dealing with these challenges will require that those involved in reprocessing—both device manufacturers and sterile processing personnel—have deeper knowledge of the science and practices that underlie reprocessing. For sterile processing personnel, it is not enough to know how to load and run a sterilizer or how to follow manufacturer’s instructions. Today, they need to understand how cleaning, disinfection, and sterilization processes are developed and validated, and they should possess at least a basic understanding of the microbiology, chemistry, and physics behind those processes. Similarly, medical device designers and manufacturers can no longer wait until a device is ready to go to market to figure out how it will be reprocessed. They need this knowledge in advance so that sterilization requirements can be appropriately addressed as part of device design, ensuring that reprocessing the devices they create in the future will be simpler, safer, and more effective.

In this textbook, Donna Swenson distills what she has learned through her education and long career in both industrial and health care sterilization, as well as through her work developing sterilization standards in the U.S. and internationally. It introduces the reader to the basic principles of disinfection and sterilization science and then shows how this science is applied to develop and validate cleaning, disinfection, and sterilization processes. By providing the reader with a good understanding of the esoteric domain of sterilization science and engineering, it is hoped that the quality and efficacy of medical devices can be improved and that patient safety may be advanced.

Joe Lewelling, vice president of standards and emerging technology,
AAMI secretary of ISO/TC 198, Sterilization of health care products
February 2014

Preface

Several years ago, I was speaking with some of my colleagues at an AAMI Sterilization Standards Committee meeting. One of the things that we discussed was how confusing the principles of sterilization verification, validation, and qualification are to many of the people who work in the sterile processing and medical device manufacturing fields. This knowledge seems to be the private domain of sterilization engineers, who appear to possess an almost esoteric knowledge of verification, validation, and qualification of sterilization processes. However, many other people are involved in sterilization, and they need to understand these principles as well. During the course of this conversation, one of my colleagues mentioned that someone needs to write a book that would explain in plain English what sterilization verification, validation, and qualification mean and how they are performed. After the conversation, everyone moved on to other things.

But, this conversation got me thinking. Over the next several months, I kept thinking about that comment that someone needs to write a book. The more I thought about it, the more I agreed that someone *did* need to write a book. I approached Joe Lewelling, AAMI's vice president of standards, and asked him whether AAMI would publish such a book. That conversation led, in turn, to a conversation with Steve Campbell, chief operating officer for AAMI. Steve and I agreed that this was a worthwhile project. In May 2011, Steve and I signed a publishing agreement and thus I began a journey that led to the publication of this book.

This book is about the principles on which sterilization verification, validation, and qualification are based. To facilitate understanding of those principles, I begin with basic information about the science behind sterilization and quality management. Next, the book covers the principles of validation and then how those principles apply to cleaning processes, the validation of steam sterilization processes, and product quality assurance testing of steam sterilization processes. Verification of cleaning and steam sterilization processes is also addressed.

This book is written as a textbook. It is meant to provide an explanation of the basic concepts of verification, validation, and qualification of sterilization processes for both healthcare facilities and medical device manufacturers. The intent of the book is to help sterile processing and medical device manufacturing personnel be on the "same page" and to be able to use the same language and concepts in discussing and understanding sterilization processes. I also expect that this book will help different groups understand each other's needs. I believe that with the help of the many reviewers and the editor, I have accomplished these goals. I am hopeful that with improved understanding of each group's requirements, we will be able to obtain medical devices that meet the needs of all involved parties: the patient, the user of the device, and the reprocessor of the device.

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Acknowledgments

Many people have helped bring this book to publication. I would first like to thank my husband, Charles (Chuck) Swenson. Without Chuck, I would never have become the person capable of writing this book. I remember that he used to introduce me to people as "Donna, my A student, my wife." In his eyes, I was and still am, first and foremost, Donna, the person he helped to become an expert on the sterilization of medical devices. Thanks for all the years of support.

Next, I would like to thank several people at AAMI. Joe Lewelling believed in me and in the importance of this book. Without his support, this book would never have been begun. I also want to thank Steve Campbell, who has worked with me for more than two years to make this book a reality. Steve listened when I said that I needed more reviewers, and he made it happen. I want to thank Judy Veale as well, who formerly participated in AAMI standards-development activities and who continues to work on various AAMI projects. This book has been one of those projects. Judy's skills as an editor have been invaluable. She has been insightful, has offered many suggestions, and has helped to clarify many points by asking questions.

Many people reviewed this book and helped make it into a better product that answers the questions that sterile processing and medical device manufacturing personnel have about sterilization verification, validation, and qualification. I don't know their names, but I am thankful for their contributions and for the time they all committed to reviewing the original and subsequent drafts of the book. Their comments helped to strengthen the book and to ensure that I actually did achieve the goals that I sent out to accomplish in its writing.

Finally, I want to thank the Publications team and everyone at AAMI who had a hand in making this happen. I know that it was a group decision to agree to publish the book and to continue to support the project over the more than two years that it has taken to write the book. The team would like to thank numerous contributors to the project, including Jonathan Wilder, for their assistance at various stages of the publication process.

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CHAPTER 1 Introduction

Healthcare sterile processing and medical device manufacturing professionals of today need a comprehensive understanding of sterilization processes and how to produce sterile product. Device manufacturers are required to provide information to the Food and Drug Administration (FDA) on how they will address the manufacturing of all products and how reusable products are to be cleaned and sterilized by the end user or sterile processing professional. For device manufacturers to fulfill this obligation, an understanding of the cleaning and sterilization processes used in health care is required. Sterile processing professionals must ensure that

- a) their sterilization processes meet quality assurance standards;
- b) they are adhering to these processes;
- c) the methods used for the products that they process are verified; and
- d) the processes used for the sterile products they create are validated.

This book is intended to be used as a textbook by medical device manufacturers, healthcare sterile processing professionals, and students of sterilization. It explains concepts and provides examples and definitions for sterilization science, quality management, validation theory, and cleaning and sterilization practices, focusing on steam sterilization as a model process for hospital application and on product quality assurance testing methods used in U.S. hospitals.