Technical Information Report

AAMI TIR100: 2021

End-to-end microbiological quality and sterility assurance

AAMI
Advancing Safety in Health Technology

End-to-end microbiological quality and sterility assurance

Approved 1 October 2021 by
AAMI

Abstract: This technical information report (TIR) provides guidance for a comprehensive framework that integrates and connects Microbiological Quality & Sterility Assurance (MQ&SA) into an organization's end-to-end process for the development, validation, and routine control of sterile health care products.

Keywords: aseptic processing, end-to-end, microbiologically controlled processing, sterility assurance, terminal sterilization, process

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. A TIR must be acted on and the action formally approved usually every three years.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-837-9

Contents

Page

Figures

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Assurance of Sterility Working Group

This technical information report was developed by the AAMI Assurance of Sterility Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

At the time this technical information report was published, the **AAMI Assurance of Sterility Working Group** had the following members:

Cochairs: Christopher Anderson
Byron Lambert

Members: Christopher Anderson, Johnson & Johnson
Edward Arscott, NAMSA
Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
Carolyn Braithwaite-Nelson, Philips
David Brodersen, Getinge USA
Trabue Bryans, BryKor LLC
Glenn Calvert, West Pharmaceutical Services, Inc.
Jeremy Criss
Sophia Czechowicz, Advanced Sterilization Products (ASP)
Elaine Daniell, EDan-SA LLC
April Doering, Cantel Inc
Gordon Ely, LexaMed Ltd
Dan Floyd, DuPont Tyvek Medical and Pharmaceutical Protection
Chad Geiger, DexCom Inc
Becky Gilsdorf, Healthmark Industries Company Inc
Dr. Zory Glaser, Johns Hopkins University-School of Public Health
Douglas Harbrecht, Sterility Assurance LLC
Deborah Havlik, DA Havlik Consulting
Jason Hedrick, Medtronic Inc Canada
Betty Howard, STERIS Corporation | Healthcare
Henri Hubert, Quality Processing Resource Group LLC
Timothy Hurtado
Nupur Jain, Intuitive Surgical Inc
Valerie Kozik, Pro-Gamby
Mark Krocko, Merck Corporation
Byron Lambert, Abbott Laboratories
John LeClair
Jeffrey Martin, Sterilization and Quality System Consulting LLC
Mauricio Martinez, Smiths Medical
Patrick McCormick, Bausch & Lomb Inc
Jami McLaren, Boston Scientific Corporation
Nicole McLees, 3M Health Care
Susan Messier, Ethide Laboratories
Vanessa Molloy-Simard, Stryker Instruments Division
Melissa Morgan
Paul Nirgenau, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Susumu Nozawa, Siemens Healthineers
Gerry O'Dell, Gerry O'Dell Consulting
Ken Paddock, Baxter Healthcare Corporation
David Parente, Sterwell LLC
Kimberly Patton, Becton Dickinson & Company
Michael Polozani, Case Medical Inc
Claudia Romero-Waas, BSI Healthcare
Tyrone Rouse, Owens & Minor

Jody Rupert, WL Gore & Associates Inc
Manuel Saavedra, Avanos Medical
Harry Shaffer, Sterilization Consulting Services
Myra Smith, FDA/CDRH
Sopheak Srun, Quality Tech Services LLC
Elizabeth Steiner, IUVO BioScience
Aiying Sun, Verrix LLC
Julie TerWee, Pfizer Parenteral Center of Excellence
Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Stephanie Volk, ConvaTec Inc QARAC Global Headquarters
Sean Weir
Dean Wellman, Midmark Corporation
Beverly Whitaker, Indigo Consulting Group LLC
Jarl Yeager, Powder River Medical Resources
Shelley Zimmerman, WuXi AppTec Inc

Alternates: Kenneth Aston, Intuitive Surgical Inc
Ralph Basile, Healthmark Industries Company Inc
Stacy Bohl, Boston Scientific Corporation
Charles Cogdill, Medtronic Inc Campus
Chris Coker, Advanced Sterilization Products (ASP)
Kimbrell Darnell, Becton Dickinson & Company
Mark Duro
Shawn Engberg, MD Furniture & Supply
Chris Haas, Getinge USA
John Harper, Sterile Edge
Nichole Jackson, Ecolab
Melinda Johnson, WuXi AppTec Inc
Satu King, Philips
Sarath Koruprolu, Ethide Laboratories
Jean-Luc Lemyre, Stryker Instruments Division
Michelle (Shelly) Luebke, Baxter Healthcare Corporation
Gerald McDonnell, Johnson & Johnson
Gloria Narsayah, Propper Manufacturing Co Inc
Brian Nissen, Quality Tech Services LLC
Mike Nolan, HIGHPOWER Validation Testing & Lab Services Inc
Janelle Pence, WL Gore & Associates Inc
Jason Pope, Sotera Health LLC
Victoria Rodriguez, FDA/CDRH
Jason Rogers, STERIS Corporation | Healthcare
Michael Schoene, Bausch & Lomb Inc
Mark Sundt, DuPont Tyvek Medical and Pharmaceutical Protection
Molly Thompson, 3M Health Care
Hemant Vekaria, Abbott Laboratories
Cynthia Vics, CSI Healthcare
Jill Warren, Siemens Healthineers
James Whitcomb, LexaMed Ltd

NOTE Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

At the time this technical information report was published, the **AAMI Sterilization Standards Committee** had the following members:

Co-chairs: Janet Prust
Patrick Weixel

Members: Gregory Aldrich
Anas Aljabo, CMC Sterilization Ltd
Brett Anderson, Cochlear Ltd
Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
Richard Bancroft, STERIS Corporation | Healthcare

Marie Brewer
Trabue Bryans, BryKor LLC
Jonathan Burdach, Nanosonics Limited
Charles Cogdill, Medtronic Inc Campus
Lena Cordie-Bancroft, Qualitas Professional Services LLC
Emily Craven, Boston Scientific Corporation
Jacqueline Daley
Gordon Ely, LexaMed Ltd
Lisa Foster, Adiuvo QS & SA Consulting
Daniel Fowler, WuXi AppTec Inc
Joel Gorski, NAMSA
Magnus Graham, BSI Healthcare
Ashley Hammer
Joyce Hansen, Johnson & Johnson
Douglas Harbrecht, Sterility Assurance LLC
John Harper, Sterile Edge
Deborah Havlik, DA Havlik Consulting
Mollie Holter, MicroBio Consulting LLC
Clark Houghtling, Cosmed Group Inc
Susan Klacik, IAHCSMM
Erin Kyle, Association of Perioperative Registered Nurses (AORN)
Byron Lambert, Abbott Laboratories
Patrick McCormick, Bausch & Lomb Inc
Leslie Nichols, Mayo Clinic
Gerry O'Dell, Gerry O'Dell Consulting
Tarika Onishi, DexCom Inc
Ken Paddock, Baxter Healthcare Corporation
Kia Parker, The Ohio State Wexner Medical Center-University Hospital
Renee Patterson, CIVCO Medical Solutions
Kimberly Patton, Becton Dickinson & Company
Janet Prust, 3M Health Care
Nancy Rakiewicz, IUVO BioScience
Joan Rickard, Montefiore Medical Center
Linda Schultz, Northside Hospital Surgical Services Atlanta
Kristen Singleton, Getinge USA
Joan Spear, Joan M. Spear (Independent Expert)
Sopheak Srun, Quality Tech Services LLC
Mark Swanson, Quality and Regulatory Expert Partners (QRX)
Julie TerWee, Pfizer Parenteral Center for Excellence
James Treharn, St Peter's Health
Marjorie Wall, Kaiser Permanente Foundation - Downey
Sean Weir
Patrick Weixel, FDA/CDRH
James Wiggs, Legacy Health System
Martell Winters, Sotera Health LLC
Roberto Zunzunegui, Philips

Alternates:
Josh Abdo, CIVCO Medical Solutions
Jennifer Benolken, DuPont Tyvek Medical and Pharmaceutical Protection
Stacy Bohl, Boston Scientific Corporation
Carolyn Braithwaite-Nelson, Philips
Greg Crego, IUVO BioScience
Kimbrell Darnell, Becton Dickinson & Company
Aaron DeMent, Sotera Health LLC
Chad Geiger, DexCom Inc
Anna Grayson, Grayson Associates
David Kelman, Sterile Edge
Michelle (Shelly) Luebke, Baxter Healthcare Corporation
Gerald McDonnell, Johnson & Johnson
David McGoldrick, Abbott Laboratories
Nicole McLees, 3M Health Care
Christine Render, Cosmed Group Inc

Jimmy Reyes, Alcon Laboratories Inc
Mary Sheehan, BSI Healthcare
Molly Swanson, Quality Tech Services LLC
Lisa Ward, STERIS Corporation | Healthcare
Jon Wood, IAHCSMM
Shelley Zimmerman, WuXi AppTec Inc

NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR100, *End-to-end microbiological quality and sterility assurance*, but it does provide important information about the development and intended use of the document.

Introduction

This AAMI Technical Information Report (TIR) was developed to describe a comprehensive framework that integrates and connects Microbiological Quality & Sterility Assurance (MQ&SA) into an organization's end-to-end process for the development, validation, and routine control of sterile health care products.

The Supply Chain for a health care product is an end-to-end process that begins and ends with the customer. The health care product requirements are established based on the specific customer needs, and, in the end, the customer is the ultimate user of the health care product. The end-to-end process is defined as the following: Research and Development (R&D), Plan, Source, Make, Deliver, & Customer (See Figure 1). Addressing MQ&SA throughout the end-to-end process is critical to ensure that the finished health care product meets its defined requirements.

Figure 1—End-to-end process

The interactions and information flow within the end-to-end process are interwoven and not necessarily linear as shown in Figure 1. For smaller companies, the same personnel could perform numerous activities whilst in a large company, there might be specific groups of individuals that perform each activity within the end-to-end process. Additionally, smaller companies might not have as definitive distinctions between the activities shown. Understanding the roles and responsibilities within the organization is important to facilitate collaboration. An example of the interactions and information flow between the individuals that provide these functions is shown in Figure 2.

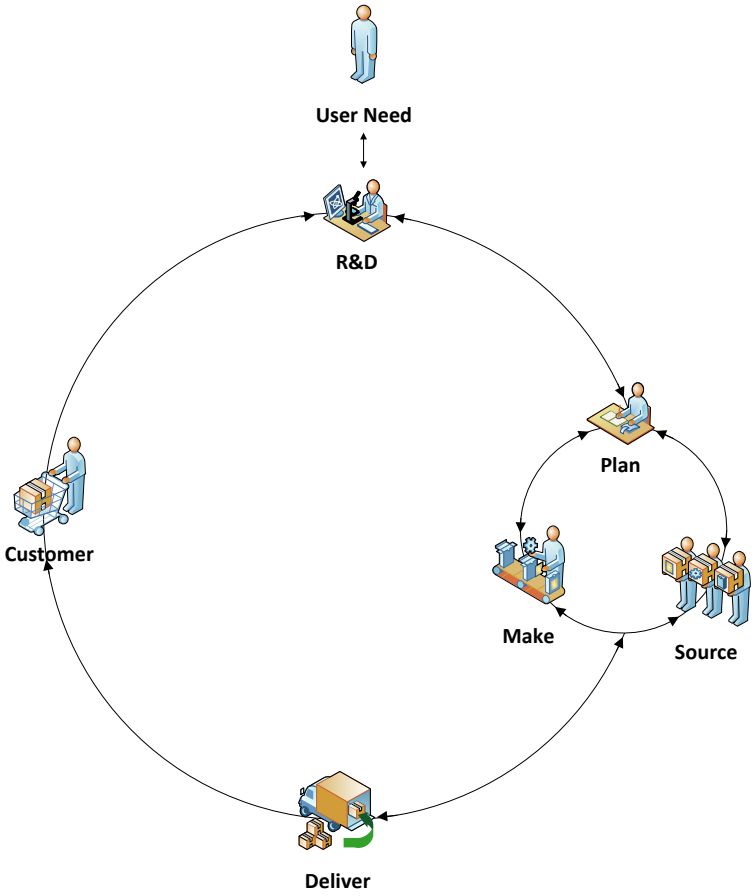

Figure 2—Interactions and information flow within the end-to-end process

Interactions and information flow between personnel that support the different aspects of the end-to-end process will ensure that the product is designed to meet customer expectations. R&D works with the customer to understand their expectations and translate their needs into product requirements. R&D in collaboration with the rest of the Supply Chain (e.g., Plan, Source, Make, and Deliver) will develop the product plan for manufacturing (a.k.a. production) and delivery to the customer. Throughout the end-to-end process, a feedback loop is important between R&D, Plan, Source, Make and Deliver to ensure the product continues to meet the needs of the customer. This collaboration and information flow can be used for internally and externally manufactured products, or during the assessment and integration of products acquired through mergers or acquisitions.

MQ&SA requirements should be integrated throughout the end-to-end process rather than just at the beginning and end of the process. For example, if during the product design phase, MQ&SA is only considered once the design has been finalized, this can have significant impact on cost or product launch timelines (e.g., launch delays) due to need to modify product design to address MQ&SA requirements identified during the final design review. In addition, if the Plan for manufacturing has already been developed, it might not include considerations for critical facility design criteria, as well as microbiological controls (e.g., air, water, personnel).

This technical information report (TIR) provides guidance on a framework that integrates and connects MQ&SA during the entire end-to-end process for terminally-sterilized and aseptically-processed products. As new product innovations challenge current terminal sterilization and aseptic processing, the need for continued focus on the end-to-end process to meet the MQ&SA needs for future products becomes more critical.

End-to-end microbiological quality and sterility assurance

1 Scope

This document provides guidance on integration of Microbiological Quality & Sterility Assurance (MQ&SA) into the end-to-end process. This framework is intended to connect the MQ&SA activities that should be addressed throughout the end-to-end process: from defining MQ&SA requirements during R&D through customer receipt and use of the product.

NOTE 1 These principles can be applied to other microbiologically controlled products. For example, certain hand care products, wound dressings, drainage bags, etc.

NOTE 2 While reusable devices are not included in the scope of this document, the general principles of design inputs, design process, design outputs, design verification and design validation can be applied.

2 Normative references

There are no normative references for this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
aseptic processing
handling of sterile product, containers, and/or the product in a controlled environment in which the air supply, materials, equipment, and personnel are regulated to maintain sterility.

[SOURCE: ISO 11139:2018, 3.14]

3.2
clean
visually free of soil and below specified levels of analytes

[SOURCE: ISO 11139:2018, 3.45]

3.3
customer
person (e.g., patient, clinician, health care provider) or organization that receives a product

3.4
deliver
provide ordered services or products to the customer

3.5
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

