Technical Information Report

AAMI TIR29: 2012

Guide for process characterization and control in radiation sterilization of medical devices

AAMI
Advancing Safety in Medical Technology

AAMI Technical Information Report

AAMI TIR29:2012
(Revision of AAMI TIR29:2002)

Guide for process characterization and control in radiation sterilization of medical devices

Approved 31 December 2012
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report provides additional guidance for characterizing the irradiation process and for establishing requisite process controls to ensure the irradiation system remains in a validated state. This document is intended to complement qualification and routine control activities as defined in ANSI/AAMI/ISO 11137 for gamma, X-ray, and electron beam sterilization.

Keywords: installation qualification, operational qualification, performance qualification, dose mapping, routine monitoring and control, irradiator validation, process effectiveness, gamma, electron beam, X-ray, e-beam

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633

Published by

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

Printed in the United States of America

ISBN 1–57020–477–2

Contents

Annexes

Figures

Tables

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

This technical information report was developed by the AAMI Radiation Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of the TIR does not necessarily imply that all committee members and working group members voted for its approval.

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

Cochairs
Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, Ph.D., Dupont Protection Technologies

Members
Christopher Anderson, Boston Scientific Corporation
Trabue D. Bryans, WuXi AppTec Inc.
Peter A. Burke, PhD, Steris Corporation
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System (Independent Expert)
Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Sinai Hospital of Baltimore (Independent Expert)
Kimbrell Darnell, CR Bard
Lisa Foster, Adiuvo QS & SA Consulting
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Worldwide Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Canadian Standards Association
Reynaldo Lopez, Cardinal Health (MP&S)
Lisa N. Macdonald, Becton Dickinson & Company
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Moog Medical Devices
Michael H. Scholla, Ph.D., Dupont Protection Technologies
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Co Inc.
Mark N. Smith, Getinge USA
Martell Krossa Winters, BS SM, Nelson Laboratories Inc.
William H. Young, Sterigenics International
William E. Young, (Independent Expert)

Alternates
Lloyd Brown, Covidien
Glenn W. Calvert, Becton Dickinson & Company
Dave Dion, Cardinal Health (MP&S)
Gordon M. Ely, WuXi AppTec Inc.
Thomas J. Frazar, Johnson & Johnson

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.

At the time this document was published, the **AAMI Radiation Sterilization Working Group** had the following members:

Cochairs
Trabue D. Bryans, WuXi AppTec Inc.
Lisa Foster, Adiuvo QS & SA Consulting

Members
Simon Bogdansky, PhD, Allosource
Curt Andrew Bogue, BAS, Cook Inc.
Harry F. Bushar, PhD, (Independent Expert)
Glenn W. Calvert, Becton Dickinson & Company
Rebecca Campbell, Sterigenics International
Mr. Vincent A. Caputo, WL Gore & Associates Inc.
Michael Cascio, Johnson & Johnson
Gary J. Chilson, Moog Medical Devices
Denise Cleghorn, Boston Scientific Corporation
Gary N. Cranston, Consulting & Technical Services/PCS
Emily Craven, Nordion Inc.
Elaine Daniell, CR Bard
Douglas D. Davie, Sterilization Validation Services
Mrs. Darci Diage, Direct Flow Medical Inc.
April J. Doering, St Jude Medical Inc.
Barry P. Fairand, PhD, (Independent Expert)
William F. FitzGerald, PE, FitzGerald & Associates Ltd
Chris Haas, Covidien
Joyce M. Hansen, JM Hansen & Associates
Thomas L. Hansen, Terumo Americas Corporate
Deborah A. Havlik, Hospira Worldwide Inc.
David King, Tandem Diabetes Care Inc.
Carolyn L. Kinsley, LexaMed Ltd
Byron J. Lambert, PhD, Abbott Laboratories
Reynaldo Lopez, Cardinal Health (MP&S)
Ronald G. Lulich, 3M Healthcare
Jeff Martin, Alcon Laboratories Inc.
John Masefield, Steris Corporation
Joseph M. Mello, Ethide Laboratories Inc.
Russell D. Mills, GE Healthcare
Larry Nichols, Nutek Corporation
Gerry A. O'Dell, MS, Gerry O'Dell Consulting
Dave Parente, NAMSA
Michelle Peterson, Stryker Instruments Division
Rudy M. Pina, Boston Scientific Labs Inc.
Manuel Saavedra, Jr., Kimberly-Clark Corporation
Zenius Veliconas, Stericon Inc.
Jon Seaman, Terumo BCT
Harry L. Shaffer, Sterilization Consulting Services
Ian Shorr, CareFusion
Jonathan Spalding, The Anspach Effort
Sopheak Srun, MPH SM(NRCM), Quality Tech Services Inc.
Richard L. Weisman, Fresenius Medical Care Renal Therapies Group
Patrick B. Weixel, FDA/CDRH
Mr. John Andrew Williams, Baxter Healthcare Corporation
Martell Kress Winters, BS SM, Nelson Laboratories Inc.

Alternates
Marjean Boyter, Fresenius Medical Care Renal Therapies Group
John Broad, NAMSA
Jonathan Bull, Becton Dickinson & Company
Claudia Camp, Stryker Instruments Division
David Cardin, Zimmer Inc.

Greg Crego, Moog Medical Devices
John DiCaro, Covidien
Dave Dion, Cardinal Health (MP&S)
Brian R. Drumheller, CR Bard
Niki Fidopiastis, Sterigenics International
Shelley Green, WuXi AppTec Inc.
Thomas Gwise, FDA/CDRH
Doug F. Harbrecht, Boston Scientific Corporation
Chris Johnson, Steris Corporation
Jim Kaiser, Bausch & Lomb Inc.
Bert Kingsbury, Terumo Americas Corporate
Ezra Koski, A, Terumo BCT
Maggie Ladd, BA BS, Kimberly-Clark Corporation
Antonio Lopez-Feliciano, CareFusion
Jody L. Markling, St Jude Medical Inc
Consuelo McChesney, Alcon Laboratories Inc.
Lorra Parliament, Becton Dickinson & Company
John F. Reger, Johnson & Johnson
Robert R. Reich, BS MS, LexaMed Ltd
Mark Seybold, Baxter Healthcare Corporation
Michael G. Sprague, Ethide Laboratories Inc.
Wendy Wangsgard, PhD, Nelson Laboratories Inc.
Casimir John Woss, PhD, FitzGerald & Associates Ltd

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

Foreword

This document is the second edition of AAMI TIR29. It is now more closely aligned with the general format/section headings of ISO 11137-1 and eliminates redundancies of ISO 11137-3. This second edition is expanded to encompass process characterization and process control, address X-ray sterilization, and provide more guidance regarding additional dose mapping studies, mapping, and processing families. It also incorporates information regarding process equivalency in cobalt-60 radiation sterilization facilities.

This TIR addresses process characterization and relevant controls in gamma, electron beam, and X-ray irradiators to ensure the radiation sterilization process for medical devices is maintained in a validated state. A critical element in the radiation sterilization process is the dose delivered to product. How the dose is delivered to the product first requires a clear understanding of the conditions under which the irradiator will be routinely operated and what studies are necessary to characterize the capabilities of the irradiator relative to the conditions of use. Once the characterization is completed and the process is validated, controls pertaining to the product and process (including equipment and instrumentation) should be established to ensure that the radiation dose is delivered in a reliable, accurate, and reproducible manner.

The reliability and consistency of the dose delivery process are ensured by controlling and monitoring critical product and process parameters. Critical product parameters will always include product density, orientation, case dimensions, loading configurations, and if applicable, orientation. Critical process parameters may be different from one radiation modality to another. For gamma sterilization, critical process parameters include, but are not limited to, the radionuclide source activity and decay rate, conveyor timer settings, source-to-product positioning, irradiator pathway, and changes in intervening products between the source and irradiation containers. For electron beam sterilization, critical process parameters include, but are not limited to, the beam characteristics (e.g., beam energy, average beam current and, if applicable, scan width and scan uniformity, pulse rate), conveyor speed, and presentation of product to the beam (e.g., single-sided, double-sided, multiple sides). For X-ray sterilization, critical process parameters are the same as those for electron beam, with the addition of the X-ray converter target characteristics (due to angular divergence of X-ray beam, converter-to-product distance may be important).

Once these parameters are established, products processed using the specified parameters will receive the specified doses. Data for determining required processing parameters for gamma, electron beam, and X-ray sterilization are obtained from tests performed during validation.

Once validated, both product and process parameters must be controlled and routinely monitored to ensure consistency and continued effectiveness of the sterilization process. Data from routine dosimetry may be analyzed using standard statistical process control techniques, and the results may be used to monitor and maintain control of the process. A properly administered program for process control helps ensure that dose is consistently and accurately delivered to products, which allows for dosimetric release and offers the possibility for parametric release of product.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of AAMI TIR29:2012, *Guide for process characterization and control in radiation sterilization*, but it does provide important information about the development and intended use of the document.

Guide for process characterization and control in radiation sterilization of medical devices

1 Scope

This technical information report (TIR) provides additional guidance for establishing and meeting the irradiator Operational Qualification (OQ), Performance Qualification (PQ), and routine control requirements for radiation sterilization as defined in ANSI/AAMI/ISO 11137-1 for gamma, electron beam, and X-ray sterilization.

NOTE—This TIR is intended to be used in conjunction with ANSI/AAMI/ISO 11137-1, *Sterilization of health care products—Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*. Because a TIR is considered "informative" and is not subject to the same formal approval process as a standard, the process steps are described in the TIR as "should" rather than "shall." Readers are reminded that many of this TIR's "shoulds" are "shalls" in ANSI/AAMI/ISO 11137-1.

2 Normative reference

The following normative document contains provisions that, through reference in this text, constitute provisions of this TIR. Subsequent amendments to or revisions of this publication do not apply. However, parties to agreements based on this TIR are encouraged to investigate the possibility of applying the most recent edition. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid International Standards.

ANSI/AAMI/ISO 11137-1:2006 Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 11137-2:2006 Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose

ANSI/AAMI/ISO 11137-3:2006 Sterilization of healthcare products – Radiation – Part 3: Guidance on dosimetric aspects

3 Terms and definitions

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

3.1 base cycle time: cycle time selected for processing groups of products.

3.2 dose uniformity: measure of the variation of dose within the process load

3.3 dose zone: volume within an irradiation container that receives doses with statistically equivalent values.

3.4 dosimeter placement grid: defined system for identifying the locations of dosimeters within irradiation containers or process loads.

NOTE—While reference may be generally made to this term throughout this document, for Installation Qualification and Operational Qualification, this is the *qualification* dosimeter placement grid, and for Performance Qualification, this is the *product* dosimeter placement grid.

3.5 effective density: bulk density multiplied by the ratio of product width to the designed maximum width where width is the dimension perpendicular to the source of radiation.

3.6 homogeneous dose map study: measurement of dose distribution performed during irradiator Operational Qualification (OQ) or requalification where only materials of the same density and configuration are irradiated.

