

Technical Information Report

AAMI TIR104: 2022

Guidance on transferring
health care products
between radiation
sterilization sources

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Guidance on transferring health care products between radiation sterilization sources

Approved 25 January 2022 by
AAMI

Abstract: Provides guidance in managing the process for transferring a health care product either from one radiation sterilization modality to another or from one irradiator to another using the same radiation modality. The specific radiation modalities addressed are gamma, electron beam, and X-ray.

Keywords: Radiation, gamma, electron beam, X-ray

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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

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Printed in the United States of America

ISBN 978-1-57020-831-7

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Committee representation

Association for the Advancement of Medical Instrumentation

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This technical information report was developed by the AAMI Radiation Sterilization 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.

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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 technical information report are invited. Comments and suggested provisions 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 TIR104, *Guidance on transferring health care products between radiation sterilization sources*, 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 and clarify the process for transferring sterilization of health care products between radiation sterilization sources and to provide additional guidance to improve the quality of decisions made during that process.

Sections 8.4 and A.8.4 of ANSI/AAMI/ISO 11137-1:2006/(R)2015 provide minimal guidance for evaluating or re-establishing maximum acceptable, verification or sterilization doses when a health care product is transferred between radiation sources. Health care products might warrant sterilization at multiple facilities and/or with different radiation modalities.

Specific guidance is provided in this TIR to assist in the process of product transfer between radiation sources, specifically in the areas of:

- defining key operating parameters and radiation characteristics for a radiation site relevant to dose delivery;
- determining conditions when a sterilization and verification dose may be transferred between radiation sites;
- establishing qualification methods when sterilization and verification doses cannot automatically be transferred between radiation sites;
- determining conditions when a maximum acceptable dose may be transferred between radiation sites;
- establishing qualification methods when maximum acceptable dose cannot automatically be transferred between radiation sites, and;
- providing guidance on documenting an assessment which confirms that the sterilization and verification and/or maximum acceptable dose do not require revalidation.

NOTE This TIR contains guidelines that are not intended to be absolute or to be applicable in all circumstances. Judgment should be used in applying the information in this TIR.

Guidance on transferring health care products between radiation sterilization sources

1 Scope

The focus of this document is to provide guidance in managing the process for transferring a health care product either from one radiation sterilization modality to another or from one irradiator to another using the same radiation modality. The specific radiation modalities addressed are gamma, electron beam, and X-ray.

Guidance in this AAMI Technical Information Report (TIR) relates to:

- assessment of change;
- evaluation of differences between radiation sources;
- assessment of sterilization and verification dose;
- assessment of maximum acceptable dose.

Certain aspects that might be important in transferring products to different radiation sterilization sources are outside the scope of this TIR. These include:

- evaluation of biocompatibility;
- toxicological risk assessment;
- irradiator radiation safety, exclusive of the potential for induced radioactivity;
- cost or financial considerations;
- supply chain risk management;
- regulatory filings.

2 Normative references

The following documents are provided for information.

ANSI/AAMI//ISO 11137-1:2006/(R)2015 and A1:2013 and A2:2019, *Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices* and Amendment 1 and Amendment 2

ANSI/AAMI//ISO 11137-2:2013/(R)2019, *Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose*

ISO 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*