Technical Information Report

AAMI TIR76: 2021

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{max}^{SD-S}

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Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{max}^{SD-S}

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AAMI

Abstract: This technical information report describes a method for substantiating a selected sterilization dose that achieves maximally a selected sterility assurance level (SAL) for radiation sterilization of healthcare products and a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

Keywords: radiation sterilization, sterilization, dose, sterility assurance level, SAL, Method VD_{max}^{SD-S}

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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 22203-1633.

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Contents

Page

Tables

Committee representation

Association for the Advancement of Medical Instrumentation

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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 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 TIR76, Sterilization of health care products—Radiation—*Substantiation of a selected sterilization dose at a specified sterility assurance level: Method* $VD_{max}^{SD\text{-}S}$ (AAMI TIR76:2021), but it does provide important information about the development and intended use of the document.

Introduction

This technical information report (TIR) is intended to be used in conjunction with ANSI/AAMI/ISO 11137-1:2006/(R)2015, *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*. One of the activities encompassed within process definition in ANSI/AAMI/ISO 11137-1 is the option to select and substantiate a sterilization dose to be applied to healthcare products.

ANSI/AAMI/ISO 11137-2:2013/(R)2019 includes Method VD_{max} for the substantiation of 25 kGy as a sterilization dose (termed Method VD_{max}^{25}) for product with an average bioburden ≤ 1,000 and Method VD_{max}^{15} for the substantiation of 15 kGy as a sterilization dose for product with an average bioburden ≤ 1.5. VD_{max} methods for the substantiation of sterilization doses of 17.5, 20, 22.5, 27.5, 30, 32.5, and 35 kGy are included in ANSI/AAMI/ISO TIR13004:2013, *Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose—Method VD_{max}* [1]. This TIR extends the methods of selection and substantiation of a sterilization dose specified in the above-described documents. For specified input values of average bioburden, selected sterilization dose, sterility assurance level (SAL), sample item portion (SIP), and number of product items to be irradiated at the verification dose, Method VD_{max} verification dose, and dose augmentation values are calculated using the web-based calculation tool (***CT***) component of this TIR. The ranges of acceptable input values are:

- average bioburden of 0.1 to 1,000,000;
- minimum sterilization dose of 3 to 36.4 kGy;
- SAL of 10^{-6}, 10^{-5}, 10^{-4}, or 10^{-3};
- SIP of 0.01 to 1.0;
- 10, 30, or 90 product items irradiated at the verification dose.

NOTE The method in this document follows similar technical steps as the methods given in ANSI/AAMI/ISO 11137-2:2013/(R)2019 for selection and substantiation of sterilization doses of 25 kGy and 15 kGy. However, the descriptive text in this TIR has been modified to better communicate the methods and hence the text occasionally differs from that in ANSI/AAMI/ISO 11137-2:2013/(R)2019.

The application of the method is not limited by production batch size or production frequency. The method is founded on and embodies the following three principles:

- existence of a direct link between the outcome of the verification dose experiment and the attainment of the selected SAL at the selected sterilization dose;
- possession of a level of conservativeness at least equal to that of the Standard Distribution of Resistances (SDR), the basis of Method 1;
- for a given bioburden, use of a maximal verification dose (VD_{max}) corresponding to substantiation of a selected sterilization dose.

This approach to sterilization dose substantiation was first outlined by Kowalski and Tallentire (1999) [2] and, from subsequent evaluations involving computational techniques (Kowalski, Aoshuang, and Tallentire, 2000) [3] and field evaluations (Kowalski et al., 2002) [4], it was concluded that the method is soundly based. An overview of the method and aspects of putting it into practice are provided in Kowalski and Tallentire (2003) [5]. Application of the Method VD_{max} approach to doses other than 25 kGy and at SAL values other than 10^{-6} is discussed in Kowalski et. al (2006) [6], (2010) [7] and Kowalski (2012) [8].

The method described here is designated as Method VD_{max}^{SD-S}, the “SD” indicating the selected minimum sterilization dose and the "-S" indicating the selected SAL; a minimum sterilization dose of 25 kGy and an SAL of 10^{-6} is designated as VD_{max}^{25-6}. Method VD_{max}^{SD-S} procedurally comprises elements that closely parallel those of dose-setting Method 1 described in ANSI/AAMI/ISO 11137-2:2013/(R)2019. One key area of difference is the number of product items used

in the verification dose experiment. In the computer evaluations referred to above, changing the verification SAL value had little effect on the substantiation outcome and this finding led to a sample size of 10 product items being chosen for subsequent field evaluations. The inclusion of sample sizes of 30 and 90 product items (based upon the “rule of three” in statistics) for the verification dose experiment in this document was made to accommodate situations where the user determines that irradiation of a larger number of samples might be beneficial. A choice of 30 or 90 product items for the verification dose experiment might be based, for example, upon a finding of a greater than usual variation in the numbers and/or types of microorganisms in bioburden determination(s) or the maturity/stability of the manufacturing process for the product undergoing sterilization dose establishment.

Manufacturers of healthcare products who intend to use this document are reminded that the requirements contained in the ANSI/AAMI/ISO 11137 series apply to the manufacture and control of production batches destined for radiation sterilization. In particular, a requirement states that products are to be manufactured in circumstances such that the bioburden is controlled. Compliance with the requirements for controlling the quality of raw materials, the manufacturing environment, the health, hygiene, and attire of personnel, and for establishing the basic properties of packaging material is essential.

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{max}^{SD-S}

1 Scope

1.1 Inclusions

This document describes a method for substantiating a selected sterilization dose that achieves maximally a selected sterility assurance level (SAL) for radiation sterilization of healthcare products. This document also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

NOTE Selection and substantiation of the sterilization dose is used to meet the requirements for establishing the sterilization dose within process definition in ANSI/AAMI/ISO 11137-1.

1.2 Application

If the decision is made to use this method of sterilization dose establishment, the method is to be followed according to the requirements (shall) and guidance (should) stipulated herein.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ANSI/AAMI/ISO 11137-1:2006/(R)2015 and A1:2013, *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*

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

ANSI/AAMI/ISO 11737-1, *Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products*

ANSI/AAMI/ISO 11737-2, *Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process*

3 Terms and definitions

For the purposes of this document, the following abbreviations, terms, and definitions apply. Additional terms and definitions are given in ANSI/AAMI/ISO 11137-1:2006/(R)2015 and ANSI/AAMI/ISO 11137-2:2013/(R)2019.

3.1
calculation tool *(CT)*
tool that calculates the Method VD_{max}^{SD-S} values required to substantiate a selected minimum sterilization dose.