Technical Information Report

AAMI TIR35: 2016/(R)2021

Sterilization of health care products—
Radiation sterilization—
Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits

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Advancing Safety in Health Technology

AAMI Technical Information Report

AAMI TIR35:2016/(R)2021
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Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits

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AAMI

Abstract: Describes approaches to the selection and auditing of a sterilization dose that may reduce the number of product items required while maintaining assurance of attaining the desired sterility assurance level (SAL). This approach addresses sampling plans for verification dose experiments and sterilization dose audits. In addition the approaches to adopting a product into an established product family are defined.

Keywords: sterility, bioburden, radiation, health care products, dose, audits, product adoption, design verification, procedures

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Association for the Advancement of Medical Instrumentation

Radiation Sterilization Working Group

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

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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.

Introduction

This technical information report (TIR) is intended to be used in conjunction with the ANSI/AAMI/ISO 11137 series. One of the activities encompassed within this series is the selection and routine auditing of the sterilization dose to be applied to health care products, and, in relation, the number of product items to be used to assure the sterility assurance level (SAL) is attained. A primary manufacturer might wish to reduce this number.

The guidance contained within this TIR provides strategies by which the primary manufacturer may reduce the total number of product items to be tested for establishing and maintaining the sterilization dose with alternative sampling plans. The approach to alternative sampling plans given in this TIR employs alternative sampling plans that are statistically equivalent to the sample size of 100 product items as described in Methods 1 and 2 of ANSI/AAMI/ISO 11137-2, even though a different number of products is tested. However, if there is a dose audit failure when using this approach, there is no provision for the augmentation of the sterilization dose. In this situation, the dose must be re-established or another validation method utilized.

The TIR also provides guidance by which the primary manufacturer may adopt new products or redesigned products into an established product family with a technical evaluation. Based upon the technical evaluation the method to be used to adopt the product into the family can be determined.

Text of this document was adapted from ANSI/AAMI/ISO 15843:2000. This document, along with the ANSI/AAMI/ISO 11137 series, supersedes ANSI/AAMI/ISO 15843:2000.

NOTE—This technical information report is not a standard and the material contained herein is not normative in nature. The committee has in a few places used the term "shall" based on their knowledge of requirements contained in relevant standards and/or regulatory requirements.

Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits.

1 Scope

This TIR describes approaches to the selection and auditing of a sterilization dose that may reduce the number of product items required while maintaining assurance of attaining the desired sterility assurance level (SAL). This approach addresses sampling plans for verification dose experiments and sterilization dose audits. Additionally, guidance for adopting a product into an existing product family and maintenance of product families is provided.

2 Normative references

ANSI/AAMI/ISO 11137-1:2006/(R) 2010 & A1:2013 Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 11137-2:2013 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

ANSI/AAMI/ISO 11737-1:2006/(R) 2011 Sterilization of health care product – Microbiological methods – Part 1: Determination of the population of microorganisms on product

ANSI/AAMI/ISO 11737-2:2009/(R) 2012 Sterilization of health care product – 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 TIR, the following terms and definitions apply:

3.1 augmentation

Action taken to increase the sterilization dose based upon the results obtained from a sterilization dose audit.

3.2 bioburden

Population of viable microorganisms on or in product and/or a sterile barrier system.

[ANSI/AAMI/ISO TIR11139:2006]

3.3 candidate product

The product being examined for adoption into an existing product family.

3.4 false positive

Test result interpreted as growth arising from the product, or portions thereof, tested when either growth resulted from extraneous microbial contamination or turbidity occurred from interaction between the product, or portions thereof, and the test medium.

[ANSI/AAMI/ISO 11137-2:2013]

3.5 health care product

Medical device(s), including *in vitro* diagnostic medical device(s), or medical product(s), including biopharmaceuticals.

[ANSI/AAMI/ISO TIR11139:2006]

