

Sterilization of health care products— Radiation sterilization— Product families and sampling plans for verification dose experiments and sterilization dose audits, and frequency of sterilization dose audits

Sterilization of health care products— Radiation sterilization— Product families, sampling plans for verification dose experiments and sterilization dose audits, and frequency of sterilization dose audits

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Abstract: Describes methods and rationale for changing the number of product units required for dose setting verification and dose audits as defined in annex B of ANSI/AAMI/ISO 11137.

Keywords: sterilization, radiation, health care products, dose, audits, design verification, procedures

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Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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.

Background of AAMI Adoption of ISO/TS 15843:2000

ISO/TS 15843:2000 (Technical Specification) was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for a technical report for the selection of a sterilization dose for a single production batch.

The United States made a considerable contribution to this report. The AAMI Radiation Sterilization Working Group of the AAMI Sterilization Standards Committee had originally initiated the development of this document in the U.S. When a committee draft had been developed, it was proposed for processing as an ISO Technical Report (type 2) and submitted for a parallel adoption as an AAMI Technical Information Report. ISO/TC 198 and AAMI approved the technical report in 2000. U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI).

TIR15843 is intended to be used in conjunction with ANSI/AAMI/ISO 11137, *Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization*. AAMI has produced other TIRs that are intended as companion documents to ANSI/AAMI/ISO 11137. These are:

- AAMI/ISO TIR13409:1996, Sterilization of health care products—Radiation sterilization—Substantiation of 25 kGy as a sterilization dose for small or infrequent production batches
- AAMI TIR17:1997, Radiation sterilization—Material qualification
- AAMI/ISO TIR15884:1998, Sterilization of health care products—Radiation sterilization—Selection of a sterilization dose for a single production batch

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Suggestions for improving this report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the ISO foreword on page x, this AAMI Technical Information Report is identical to ISO/TS 15843:2000.
