Technical Information Report

AAMI TIR22:2007
and
AAMI TIR22:2007/A1:2008

Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices— Part 1 and Part 2:2006

Association for the Advancement of Medical Instrumentation

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The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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AAMI Technical Information Report

AAMI TIR22:2007
(Revision of AAMI TIR22:1998
and TIR22:1998/A1:2001)

Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices—Part 1 and Part 2:2006

Approved 20 March 2007 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI Technical Information Report (TIR) provides interpretive guidance for the application of ANSI/AAMI/ISO 11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging* as well as for ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation and requirements for forming, sealing, and assembly processes.*

Keywords: barrier systems, closure, expiry date, microbial barrier, packaging system, validation

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

NOTE—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

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International designation	U.S. designation	Equivalency
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

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This AAMI Technical Information Report (TIR) was developed by the Sterilization Packaging Working Group of the AAMI Sterilization Standards Committee. Committee approval of the TIR does not necessarily imply that all committee and working group members voted for its approval.

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Foreword

ANSI/AAMI/ISO 11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* and ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes* have been recognized as the global harmonized standards for packaging of terminally sterilized medical devices. Application of these two standards must be done in compliance with the regulatory requirements within the country or region where the sale of the medical device occurs.

ISO 11607-1:2006 and ISO 11607-2:2006 were developed by ISO Technical Committee (TC) 198, *Sterilization of health care products*, to fill a need for international standards for packaging for terminally sterilized medical devices. U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group (TAG) for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). The United States made considerable contributions to the standards.

This Technical Information Report (TIR) is intended to provide guidance to the users of ANSI/AAMI/ISO 11607-1:2006 and 11607-2:2006 within the regulatory framework of the United States Food and Drug Administration. Additional guidance may be provided in specific areas for regulatory requirements outside of this jurisdiction.

This TIR is a revision of AAMI TIR22:1998 and AAMI TIR22/A1:2001, which provided guidance to ANSI/AAMI/ISO 11607:1997. The latter has been replaced by the aforementioned 11607-1 and -2 standards.

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Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices—Part 1 and Part 2:2006

1 Scope

This document specifically provides guidance on the application of ANSI/AAMI/ISO11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes* within the regulatory framework of the United States Food and Drug Administration that exists at the time of the publication of this document. A significant portion of this guidance can be applied to other regulatory frameworks that exist globally but the user must use their expertise in making the appropriate judgment on applicability.

2 Applicability and use

This document should be used in conjunction with ANSI/AAMI/ISO 11607-1:2006 and 11607-2:2006. Guidance to specific paragraphs/sections of the ANSI/AAMI/ISO 11607 standards requirements is noted. Sections 1–5 are general information; Sections 6-10 reflect the steps to be taken in developing the initial design; Section 11 gives guidance to those making a preformed sterile barrier system and to those who direct the filling and closing process of sterile barrier systems; Section 12 focuses on the evaluation of the completed and filled sterile barrier and packaging systems; and Section 13 addresses revalidation. The annexes contain educational information and references that are of interest at multiple steps or sections of this document.

3 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this TIR. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this TIR are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For updated references, the latest edition of the normative document referred to applies. AAMI maintains registers of currently valid AAMI technical documents.

3.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging,* ANSI/AAMI/ISO 11607-1:2006. Arlington (Vir.): AAMI, 2006. American National Standard.

3.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes,* ANSI/AAMI/ISO 11607-2:2006. Arlington (Vir.): AAMI, 2006. American National Standard.

3.3 ASSOCIATION FOR THE ADVANCMENT OF MEDICAL INSTRUMENTATION. *Medical devices—Application of risk management to medical devices*, ANSI/AAMI/ISO 14971:2007. Arlington (Vir.): AAMI, 2007. American National Standard.

3.4 ASTM. *Standard guide for accelerated aging of sterile medical device packages,* ASTM F1980-02. West Conshohocken (Penn.): ASTM.

3.5 ASTM. *Standard test method for seal strength of flexible barrier materials,* ASTM F88-06. West Conshohocken (Penn.): ASTM.

3.6 TAPPI Dirt estimation chart. Norcross (Ga.): TAPPI, 2000.

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3.7 U.S. FOOD AND DRUG ADMINSTRATION. *Quality System Regulation Guidance on packaging (Medical device quality systems manual: A small entity compliance guide*, *Section 13 Packaging*; http://www.fda.gov/cdrh/dsma/gmpman.html)

4 Definitions

For the purposes of this TIR, additional guidance on the definitions within ANSI/AAMI/ISO 11607-1:2006 and -2:2006 are not necessary.

5 General requirements

5.1 Quality systems

5.1.1 The application of ANSI/AAMI/ISO 11607-1:2006 should be performed within a formal quality system. (ANSI/AAMI/ISO 11607-1:2006, 4.2)

5.1.2 A critical element of this quality system is design control. Design control procedures are intended to ensure that the design of the packaging system and any modifications or revisions meet the specified design requirements (ANSI/AAMI/ISO 11607-1:2006, 6.2.1; FDA Quality System Regulation 820.30).

For further information on developing the specified design requirements see Section 6 and Annex D on design inputs.

5.1.3 The design history file typically provides documentation of the packaging system development process and any later modifications or revisions. (ANSI/AAMI/ISO 11607-1:2006, 4.5 and 6.2.5)

5.1.4 A fundamental requirement of many quality systems is risk management. A formal risk analysis should be conducted to anticipate the possible failures that can occur in the packaging process and their effects on the safety and efficacy of the device. ANSI/AAMI/ISO 14971:2007 describes the requirements and applicability of risk assessment within the scope of medical devices. Tools for conducting risk analysis are described in Annex H.

5.1.5 For references on regulatory frameworks, design controls and other quality system aspects see Annex A.

5.2 Test methods

5.2.1 All test methods must be validated. (ANSI/AAMI/ISO 11607-1:2006, 4.4.1)

5.2.1.1 Test methods that have been subjected to rigorous inter-laboratory studies may be preferred since the repeatability and reproducibility have been determined. When incorporating these methods into a specific laboratory it is important to demonstrate the accuracy and repeatability of the method are at least as good as the reproducibility from inter-laboratory studies.

5.2.1.2 Test methods developed independently or from the scientific literature may be used. However it is important to determine if the test method meets the required sensitivity and that the accuracy and repeatability meet predetermined criteria.

5.2.1.3 For guidance on test method validation see Annex B.

5.2.2 For guidance on frequently employed test methods see Annex E.

5.3 Sampling

Sampling plans should be applicable to packaging systems, reflective of risk tolerance, and be based on statistically valid rationale. (ANSI/AAMI/ISO 11607-1:2006, 4.3). See 12.2.3 for further information.

6 Design inputs

6.1 Prior to considering materials and/or packaging system design, a set of design inputs should be developed. (ANSI/AAMI/ISO 11607-1:2006, 6.2.2-6.2.3) These will be used in assessing the materials and/or design.

6.2 The design inputs will include information from multiple functions such as engineering, manufacturing, marketing, regulatory, etc.

6.3 Some examples of design inputs are device attributes, device protection requirements, sales unit configuration, sterilization process, distribution, handling, and use environment. (ANSI/AAMI/ISO 11607-1:2006, 6.1–6.2)

6.4 For guidance on developing these design inputs see Annex D.

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7 Selection and evaluation of materials

There are multiple areas of consideration when evaluating and selecting packaging system materials for a specific device packaging system application (ANSI/AAMI/ISO 11607-1:2006, 5). Additional information on these topics may be found in Annex E.

7.1 Sterilization requirements (ANSI/AAMI/ISO11607-1:2006, 5.1.6(e) and 5.3)

When assessing the material characteristics important to the device, process, and end use, it is critical to keep in mind that the material must also have the characteristics appropriate for the sterilization process (e.g., porosity for gaseous sterilization) as well as be able to withstand the rigors of the sterilization process. There are further details on sterilization in Annex C.

7.2 Safety requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.5 and 5.1.6)

When choosing a material for a medical device packaging system application there are basic safety requirements that should be met. The source, history and traceability of materials should be known and controlled. Chemical properties should be evaluated. This will typically include toxicity and an evaluation of possible chemical interactions between material and device. Testing for the presence of heavy metals is often included. Further details are provided in Annex E.

7.3 Barrier requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.4 and 5.1.6)

The barrier requirements of the device and the chosen sterilization method will help define the appropriate packaging system materials. Various methods may be used to assess the material characteristics and evaluate the barrier levels required to protect the device. Some of the areas to consider include porosity, microbial barrier, oxygen, moisture, and light transmission. These are detailed in the section on barrier in Annex E.

7.4 Visibility and appearance requirements

Visibility and appearance requirements, if applicable, will be determined by the desired aesthetics (for example a sterile barrier system with high gloss versus one with a matte finish), labeling approach (for example, a label insert may require a sterile barrier system with good clarity), and the desire to see (or mask) the device. Areas to consider are haze, gloss, opacity, and clarity; further information is in Annex E.

7.5 Durability requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.6(c), 5.1.7(e), and 6.3.2)

The sterile barrier system must be capable of protecting the device's sterility, efficacy, and/or functionality until time of use. The durability requirements will depend upon the mass and profile of the device, the type of protective packaging (if applicable), and the transport system. There are several factors that impact durability, including resistance to puncture, abrasion, and tear; flexural ability; thickness; and basis weight. These factors are detailed further in Annex E. Test methods to assess durability will characterize the material, but are not directly predictive of completed sterile barrier system durability and further evaluation, such as laboratory simulated packaging system performance tests, frequently need to be performed to assess material performance for a specific device.

7.6 Heat sealability requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.6(d) and 5.1.8(c))

Seals should be tested for tensile peel strength and reviewed to determine if the results meet the desired seal strength for the sterile barrier system. This process is typically used as a screening tool for selection of material combinations and may be used to evaluate pre and post sterilization heat sealability. (Refer to ASTM F88 for seal strength testing, including information on the effect of differences in technique).

7.7 Processing requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.2 - 5.1.9)

As packaging materials are evaluated for compatibility with equipment and processing conditions, consideration needs to be given to predetermined requirements which ensure consistent and reliable production of sterile barrier systems. Common methods used to assess process requirements and conditions are dimensional measurements, coefficient of friction (COF), sealability, and coat weight: these are discussed in more detail in Annex E.

7.8 Printing requirements (ANSI/AAMI/ISO 11607-1:2006, 5.4)

It is important to keep in mind the attributes of the packaging system materials when designing the print. Font sizes or styles may be inappropriate for specific substrates, print color(s), artwork placement and copy should also be considered. Evaluations of new substrates need to consider the ability to be printed. Printed ink properties need to ensure physical and chemical resistance to degradation, and printed process indicators must function for the intended exposure or sterilization process. Thought should be given to printing before and/or after forming to guarantee that the graphical appearance is not significantly altered and the information to be conveyed is not rendered illegible. For further information on evaluating materials for specific printing requirements see Annex E.

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7.9 Cleanliness and particulate requirements (ANSI/AAMI/ISO 11607-1:2006, 5.1.7(d))

Typical cleanliness expectation is that packaging system materials should be reasonably free of dirt, dust, grease, and other forms of contamination. Particulates may be embedded or loose, foreign or bits of parent material. For further information on particulates see Annex E. The level of particulate inherently present will be dependent upon the packaging material chosen. Size of particulate is frequently estimated using a TAPPI Dirt Estimation Chart.

7.10 Device-packaging system interaction

Material stiffness, sticking, discoloration or other attributes could interact with the device use.

7.11 Self seal peelable preformed sterile barrier system requirements

In certain use environments preformed sterile barrier systems are not closed by heat sealing but rather by the use of pressure sensitive adhesive. In this case, in order to maintain sterility of the item, self seal packages must seal completely when folded as indicated by the manufacturer of the self seal package.

8 Sterile barrier system and protective packaging design (packaging system development)

8.1 Key elements in the design

8.1.1 Use documented procedures for the design and the development of the sterile barrier system and protective packaging. (ANSI/AAMI/ISO 11607-1:2006, 6.2.1)

8.1.2 A key component of the packaging system design process is gathering and assessing the design inputs (ANSI/AAMI/ISO 11607-1:2006, 6.2.2–6.2.3), these have been previously covered in Section 6 and Annex D.

8.1.3 The package development function should be included in the design control system or process. Begin the process of designing a packaging system for a terminally sterilized medical device very early in the overall device development cycle. It is important to be engaged in the device development process and have a keen understanding of all of the attributes of the device, including all relevant device, sterilization and manufacturing specifications.

8.1.4 Sterile barrier system and protective packaging (i.e., packaging system) design may be done in conjunction with a contract manufacturer. Guidance on the use of contract packagers may be found in Annex I.

8.2 Steps in packaging system design

8.2.1 Design sterile barrier system

8.2.1.1 The goal of the package design process is a sterile barrier system which allows the device to be sterilized, maintains sterility to the point of use or expiry date and allows the device to be presented in an aseptic manner at the point of use if required. (ANSI/AAMI/ISO 11607-1:2006, 6.1-6.2)

8.2.1.2 Select the type of sterile barrier system and the materials of construction based on the information (design inputs) gathered through participation in the device development process. Some common sterile barrier system types are:

a) Those requiring only closure seals

i) Preformed tray and lid (ANSI/AAMI/ISO 11607-1:2006, A.3.2)

ii) Preformed pouch (ANSI/AAMI/ISO 11607-1:2006, A.3.3)

iii) Preformed sterilization bag (ANSI/AAMI/ISO 11607-1:2006, A.3.4)

iv) Preformed header bag (ANSI/AAMI/ISO 11607-1:2006, A.3.5)

v) Reusable containers (ANSI/AAMI/ISO 11607-1:2006, A.3.12)

b) Self-contained products with tortuous path closures (ANSI/AAMI/ISO 11607-1:2006, A.3.11)

c) Those requiring fabricating of sterile barrier system and making all seals - Form-fill-seal (ANSI/AAMI/ISO 11607-1:2006, A.3.6)

8.2.1.3 Specify and document the materials, dimensions, tolerances, geometry and physical characteristics of the sterile barrier system, in accordance with the procedures outlined in the quality system.

NOTE—Assure tolerances are reasonable for the supplier capabilities.

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8.2.2 Design protective packaging

8.2.2.1 The protective packaging provides physical protection to the sterile barrier system and its contents.

8.2.2.2 Specify and document the materials, dimensions, geometry, and physical characteristics of the protective packaging, in accordance with the procedures outlined in the quality system.

8.2.2.3 Prototype the packaging system.

8.2.2.3.1 If assessment is successful, proceed to feasibility testing.

8.2.2.3.2 If the prototype packaging system is unacceptable, return to the design phase.

8.2.3 Labeling considerations for the packaging system design

NOTE—The design and printing of labeling is a critical and time-consuming activity in the medical device industry. The responsibility for specifying the labeling content is not generally the sole responsibility of the packaging area or group. Assuring that this specified labeling is incorporated into the packaging system is usually the responsibility of the packaging area or group.

8.2.3.1 The completed labeling system has to remain intact and legible at the point of use, be compatible with all materials and processes, and not transfer to the device or react with the packaging system in a way that impairs the utility of the packaging system.

8.2.3.2 Determine if labeling will be accomplished by printing directly on the packaging materials or by affixing labels to the packaging system.

8.2.3.3 If labels are used, specify the dimensions of die cut label stock, materials, coatings, and adhesives.

8.2.3.4 If labels are used, determine whether they will be pre-printed or printed on the manufacturing floor.

8.2.3.5 Specify the type of printing to be used. Printing types include but are not limited to laser, ink jet, and thermal transfer.

8.2.3.6 If necessary, specify system of printing variable device information on the labels. Variable information includes but is not limited to lot or serial number, manufacturing date, and expiry date.

8.2.3.7 Incorporate instructions for use (IFU) and any included device literature into the packaging system design.

9 Packaging process feasibility evaluation

9.1 Feasibility evaluation for initial and full-scale packaging process

Evaluate the feasibility of both the initial and full-scale packaging process for the type of packaging system chosen in 8.2.1 and 8.2.2. Typical considerations are listed below. At this point, use of a contract packager may also be appropriate; for guidance on the use of a contract packager, see Annex I.

9.1.1 Projected volume

Primarily due to costs of equipment, smaller volume items are generally packaged in preformed sterile barrier systems, and very high volume items are often packaged in a form fill seal process. An exception to this may be if form fill seal equipment already exists that has capacity for this item. See 9.1.4.

9.1.2 Equipment/staff availability

If packaging line already exists, assess if there is capacity available for projected volume of this item.

9.1.3 Capital requirements

9.1.3.1 If a packaging line with capacity for the projected volume of this item exists, calculate the estimated costs of training applicable personnel, purchasing any new tooling, and validating this packaging system.

9.1.3..2 If a new line is required, calculate the estimated costs of new equipment and its ancillary requirements (e.g., space, electricity, and compressed air), personnel and their training, and validation of the packaging line and of this particular packaging system.

9.1.4 Total packaging system cost

(It may be helpful to define process (9.2) first). Add together:

a) Costs of components, including any anticipated waste created in sealing process

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b) Costs of fabricating/sealing, including initial equipment and running costs

c) Cost of direct labor

d) Costs of quality assurance/engineering and other support staff

e) Costs of any additional labeling or marking

f) Costs of protective packaging required for particular type of sterile barrier system, allocated over units per secondary package or further packaging

g) Sterilization cost per sterile barrier system. Consider that different packaging system volumes or configurations may result in different utilization rates of sterilization process.

9.2 Sterile barrier system process

Define process for sterile barrier system type chosen. Map or flow chart the process. Show each stage of the fabricating, loading, sealing, and packing process. Indicate packaging system material and device movement.

9.3 Equipment IQ requirement

Determine equipment IQ requirements for each stage/piece of equipment defined in process map or flowchart (9.2). See ANSI/AAMI/ISO 11607-2:2006, 5.2 for discussion of IQ as well as Section 11 below.

9.3.1 If using existing equipment, determine whether new or current tooling will be used and assess IQ accordingly.

9.3.2 If using new equipment, perform IQ.

9.4 Process parameters

Determine process parameters for each piece of equipment defined in 9.2

Use tools such as design of experiments to determine the process parameters.

9.5 Prototype or trial runs

Run sterile barrier system components at chosen process parameters to move into sterile barrier system performance testing. Build sterile barrier systems to use for sterile barrier system performance testing.

10 Sterile barrier system design feasibility evaluation

NOTE—Feasibility is not a requirement of ANSI/AAMI/ISO 11607-1:2006 or -2:2006. This section is used to assess the feasibility of the packaging system.

10.1 Sterile barrier system design feasibility evaluation performance

10.1.1 This is an engineering evaluation in which the sterile barrier system (possibly only a prototype at this point) is subjected to testing. Results of this testing determine if the design is worth pursuing.

10.1.2 This testing typically assesses:

a) Whether the sterile barrier system contained the device and protected it from being physically damaged.

b) Possible interactions between sterile barrier system and contents.

10.1.3 While this step is frequently not a full-scale validation, useful guidance may be found in Annex G, Generating a final packaging system validation protocol.

10.2 Sterile barrier system test method

Use a documented test plan employing validated test methods. (ANSI/AAMI/ISO 11607-1:2006, 6.3.2) See Annex E for further information on test methods.

10.2.1 This test plan should include pass-fail criteria.

10.2.2 Sterile barrier system tests should be conducted on samples that have been built considering the worst case elements laid out in 10.3. (ANSI/AAMI/ISO 11607-1:2006, 6.3.4)

10.2.3 Samples should be exposed to dynamic testing which simulates the expected distribution environment. (ANSI/AAMI/ISO 11607-1:2006, 6.3.5)

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10.3 Worst case feasibility condition

To properly determine feasibility, determine worst case conditions, or what at this point in the process are believed to be worst case, for a number of factors related to the packaging system. These include but are not limited to:

a) Sterile barrier system manufacturing (sealing parameters, etc.)

b) Sterilization (parameters, number of cycles, etc.) It may not be necessary for the samples to be sterilized for feasibility testing.

c) Shipping configuration. This requires an understanding of how the device will be shipped to the customer.

d) Distribution environment. This requires an understanding of how the device will be shipped to the customer.

e) Shelf life testing is usually not required at this point; however accelerated aging may be used. Accelerated aging testing allows the simulation of the effects of time on a packaging system by subjecting the fully processed protective packaging system to elevated temperatures in a controlled environment. Real time is generally estimated by assuming the degradation of packaging materials follows the kinetics described by the Arrhenius reaction rate function. See ASTM F1980 for further guidance.

10.4 Pass/fail status of packaging system

Upon completion of the testing, determine whether the packaging system passed or failed.

10.4.1 The packaging system passes the feasibility testing if the packaging system met all criteria set forth in the test plan. This establishes confidence that the design will work. Begin preparing for packaging system validation, typically performed on a validated manufacturing process as in Section 11.

10.4.2 If the packaging system failed to meet all of the criteria set forth in the test plan, the failure modes should be determined and investigated. Corrective action(s) for the failures should be put in place. This may include redesigning the concept and repeating feasibility. Guidance on determining failure mode and appropriate corrective action may be found in Annex F.

11 Validation of sterile barrier system manufacturing process

Note—Up to this point the responsibility has resided primarily with the designer of the sterile barrier system. However, the validation of the sterile barrier system involves reducing to practice the creation of an effective packaging system, and this will often mean the involvement of additional functional elements of the device manufacturer, and/or contract packagers and packaging suppliers. In the case of preformed sterile barrier systems, the construction of the sterile barrier system in the specified materials and evidence for validation of the process of making preformed sterile barrier systems of those materials is the responsibility of the sterile barrier system supplier, and the medical device packager's process validation responsibility is limited to the filling and application of a sterile barrier system closure seal. In the event a form-fill-seal method is employed, the device packager assumes responsibility for demonstrating the validation of the sterile barrier system formation and the closure following insertion of the device. Review this guidance along with ANSI/AAMI/ISO 11607-2:2006.

11.1 Development of written process validation protocol

11.1.1 Validation protocols may be written for sterile barrier system families. The rationale for determining the sterile barrier system families to evaluate should be documented.

11.1.2 Often historical data exists for specific material combinations. This information should be evaluated to determine if it is appropriate for use. Document the rationale.

11.1.3 Installation qualification (IQ) activities shall be planned and documented. If an installation qualification has been previously performed on the equipment of interest, this work should be assessed to determine if it meets the needs of the current validation activities.

11.1.4 Operational qualification (OQ) activities shall be planned and documented. The acceptance criteria shall be detailed. These predefined requirements generally include dimension, seal strength, seal integrity, opening features, and material integrity.

11.1.5 Performance qualification (PQ) activities shall be planned and documented. The acceptance criteria shall be detailed. These predefined requirements generally include dimension, seal strength, seal integrity, opening features, and material integrity.

11.1.6 The process validation protocol shall be reviewed and approved by appropriate personnel.

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