American National Standard

ANSI/AAMI/ISO 11607-2:2006/(R)2010

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes

AAMI
Association for the Advancement of Medical Instrumentation

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.

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In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

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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.

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American National Standard

ANSI/AAMI/ISO 11607-2:2006/(R)2010
(Revision of ANSI/AAMI/ISO 11607:2000)

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes

Approved 9 December 2005 by
Association for the Advancement of Medical Instrumentation

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Abstract: Specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized and maintain sterility to the point of use. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems, and packaging systems.

Keywords: barrier system, qualification, validation

AAMI Standard

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Glossary of equivalent standards

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 60601-2-04:2002	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 TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC TR 62348:200x[1]	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 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	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	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
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	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	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
ISO TS 10993-19:200x[1]	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO TS 10993-20:200x[1]	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:200x[1]	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:200x[1]	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:200x[1]	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 200x[1]	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 200x[1]	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11138-4: 200x[1]	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 200x[1]	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 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	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 TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	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 17665-1:200x[1]	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:200x[1]	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

[1]In production

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Packaging Working Group

The adoption of ISO 11607-2:2006 as an American National Standard was initiated by the AAMI Packaging Working Group of the AAMI Sterilization Standards Committee. The AAMI Packaging Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Packaging Working Group (U.S. Sub-TAG for ISO/TC 198/WG 7) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Packaging Working Group** had the following members:

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

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Background of AAMI adoption of ISO 11607-2:2006

As indicated in the foreword to the main body of this document (page x), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

ISO 11607-2 was developed by ISO Technical Committee 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 a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of the final Draft International Standard (FDIS) of ISO 11607-2:2006, the AAMI Packaging Working Group (WG) decided to adopt ISO 11607-2 verbatim as a revision, with 11607-1:2006, of ANSI/AAMI/ISO 11607:2000, now split into two parts—Part 1 on general requirements, and this Part 2 standard.

ANSI/AAMI/ISO 11607-2 describes the validation requirements for forming, sealing, and assembly processes. One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

The first and second editions of the ISO packaging standard consisted of only one document, but with the third edition, ISO/TC 198 decided to create two parts. Part 1 deals with requirements for materials, sterile barrier systems, and packaging systems. Part 2 deals with requirements for forming, sealing and assembly processes**.** The change that is perhaps the most significant and the one which cleared the way for harmonization was the establishment of new definitions for four key concepts. The definitions of “sterile barrier system,” “preformed sterile barrier system,” “protective packaging,” and “packaging system” provide for more specific descriptions and eliminate any confusion due to the way the work packaging is used in different languages. It is hoped that this new vocabulary is adopted throughout the industry and that it makes for clearer communication, especially when international collaboration is required.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard 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 American National Standard is identical to ISO 11607-2:2006.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11607-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11607-1 and ISO 11607-2 cancel and replace ISO 11607:2003, which has been technically revised.

ISO 11607 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

— *Part 1: Requirements for materials, sterile barrier systems, and packaging systems*

— *Part 2: Validation requirements for forming, sealing, and assembly processes*

Introduction

Medical devices delivered in a sterile state should be designed, manufactured and packed to ensure that they are sterile when placed on the market and remain sterile, under documented storage and transport conditions, until the sterile barrier system is damaged or opened. Additionally, medical devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation program demonstrating the efficacy and reproducibility of all sterilization and packaging processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are forming, sealing, capping or other closure systems, cutting and process handling. This part of ISO 11607 provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. ISO 11607-1 and ISO 11607-2 are designed to meet the Essential Requirements of the European Medical Device Directives.

One significant barrier to harmonization was terminology. The terms “package,” “final package,” “final pack,” “primary pack,” and “primary package” all have different connotations around the globe and choosing one of these terms to be the harmonized basis for this part of ISO 11607 was considered a barrier to successful completion of this document. As a result, the term “sterile barrier system” was introduced to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to healthcare facilities for use in internal sterilization are considered as medical devices in many parts of the world.

Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

1 Scope

This part of ISO 11607 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems, and packaging systems.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized.

This part of ISO 11607 does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements may also be necessary for drug/device combinations.

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.

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
expiry date
indication of the date, by which the product should be used, expressed at least as the year and month

3.2
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2006]

3.3
labeling
written, printed, electronic or graphic matter affixed to a medical device or its packaging system; or accompanying a medical device

NOTE Labeling is related to identification, technical description and use of the medical device but excludes shipping documents.

3.4
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO/TS 11139:2006]

3.5
packaging system
combination of the sterile barrier system and protective packaging

[ISO/TS 11139:2006]

3.6
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[ISO/TS 11139:2006]

3.7
preformed sterile barrier system
sterile barrier system that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags, and open reusable containers

[ISO/TS 11139:2006]

3.8
process development
establishing the nominal values and limit(s) for critical process parameters

3.9
product
result of a process

[ISO 9000:2000]

NOTE For the purpose of sterilization standards, product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) and health care product(s).

[ISO/TS 11139:2006]

3.10
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use

[ISO/TS 11139:2006]

3.11
repeatability
closeness of the agreement between the results of successive measurements of the same particular quantity subject to measurement (measurand) carried out under the same conditions of measurement

NOTE 1 These conditions are called repeatability conditions.

NOTE 2 Repeatability conditions can include the following:

— the same measurement procedure;

— the same observer;

— the same measuring instrument, used under the same conditions;

— the same location; and

— repetition over a short period of time.

NOTE 3 Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

NOTE 4 Adapted from *International Vocabulary of Basic and General Terms in Metrology*,1993, definition 3.6.

3.12
reproducibility
closeness of the agreement between the results of measurements of the same particular quantity subject to measurement (measurand) carried out under changed conditions of measurement

NOTE 1 A valid statement of reproducibility requires specification of the conditions changed.

NOTE 2 The changed conditions may include:

— principle of measurement;

— method of measurement;

— observer;

— measuring instrument;

— reference standard;

— location;

— conditions of use; and

— time.

NOTE 3 Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results.

NOTE 4 Adapted from *International Vocabulary of Basic and General Terms in Metrology*,1993, definition 3.7.

3.13
reusable container
rigid sterile barrier system designed to be repeatedly used

3.14
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

[ISO/TS 11139:2006]

3.15
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

NOTE An example of sterile fluid-path packaging would be the interior of the tubing for administration of an intravenous fluid.

3.16
validation
〈process〉 documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

NOTE Adapted from ISO/TS 11139:2006.

4 General requirements

4.1 Quality systems

4.1.1 The activities described within this part of ISO 11607 shall be carried out within a formal quality system.

NOTE ISO 9001 and ISO 13485 contain requirements for suitable quality systems. Additional requirements may be specified by countries or regions.

4.1.2 It is not necessary to obtain third-party certification of the quality system to fulfill the requirements of this part of ISO 11607.

4.1.3 Health care facilities may use the quality system required by their country or region.

4.2 Sampling

The sampling plans used for selection and testing of packaging systems shall be applicable to the process being evaluated. Sampling plans shall be based upon a statistically valid rationale.

NOTE Examples of suitable sampling plans are specified in ISO 2859-1 or ISO 186. Additional sampling plans may be specified by countries or regions.

4.3 Test methods

4.3.1 All test methods used to show compliance with this part of ISO 11607 shall be validated and documented.

NOTE Annex B in ISO 11607-1:2006 contains a list of suitable test methods.

4.3.2 Test method validation shall demonstrate the suitability of the method used. The following elements shall be included:

— establishment of a rationale for the selection of the appropriate tests for the packaging system;

— establishment of acceptance criterion;

NOTE Pass/fail is a type of acceptance criterion.

— determination of test method repeatability;

— determination of test method reproducibility;

— determination of test method sensitivity for integrity tests.

4.3.3 Unless otherwise specified in the test methods, test samples shall be conditioned at (23 ± 1) °C and (50 ± 2) % relative humidity for a minimum of 24 h.

4.4 Documentation

4.4.1 Demonstration of compliance with the requirements of this part of ISO 11607 shall be documented.

4.4.2 All documentation shall be retained for a specified period of time. The retention period shall consider factors such as regulatory requirements, expiry date and traceability of the medical device or sterile barrier system.

4.4.3 Documentation of compliance with the requirements may include, but is not limited to, performance data, specifications, test results from validated test methods, and protocols and results from IQ, OQ, PQ.

4.4.4 Electronic records, electronic signatures, and handwritten signatures executed to electronic records that contribute to validation, process control or other quality decision-making processes shall be reliable.

5 Validation of packaging processes

5.1 General

5.1.1 Preformed sterile barrier systems and sterile barrier system manufacturing processes shall be validated.

Examples of these processes include, but are not limited to:

— rigid and flexible blister forming;

— pouch, reel, or bag forming and sealing;

— form/fill/seal automated processes;

— kit assembly and wrapping;

— assembly of sterile fluid-path products ;

— tray/lid sealing;

— filling and closing of reusable containers;

— sterilization sheets folding and wrapping

5.1.2 Process validation shall include, at a minimum, an installation qualification, an operational qualification, and a performance qualification in this order.

5.1.3 Process development, while not formally part of process validation, should be considered as an integral part of forming and sealing (see Annex A).

5.1.4 Validation of existing products may rely on data from previous installation and operation qualification. That data can be used for determination of the tolerances for critical parameters.

5.1.5 When similar preformed sterile barrier systems and sterile barrier system manufacturing processes are validated, a rationale for establishing similarities and identifying the worst case configuration shall be documented. As a minimum, the worst case configuration shall be validated to determine compliance with this part of ISO 11607.

NOTE For example, similarity could be established by different sizes of preformed sterile barrier systems.

5.2 Installation qualification (IQ)

5.2.1 Installation qualification shall be performed.

Some installation qualification considerations are:

— equipment design features;

— installation conditions such as wiring, utilities, functionality, etc.;

— safety features;

— equipment operating within the stated design parameters;

— supplier documentation, prints, drawings, and manuals;

— spare-parts lists;

— software validation;

— environmental conditions such as cleanliness, temperature, humidity;

— documented operator training;

— operating manual or procedure.

5.2.2 Critical process parameters shall be defined.

5.2.3 Critical process parameters shall be controlled and monitored.

5.2.4 Alarms, warning systems, or machine stops shall be challenged in the event that critical process parameters exceed predetermined limits.

5.2.5 Critical process instruments, sensors, displays, controllers, etc. shall be certified as calibrated and have written calibration schedules. Calibration should be performed before and after performance qualification.

5.2.6 There shall be written preventive maintenance and cleaning schedules.

5.2.7 The application of software systems, such as programmable logic controller, data collection, and inspection systems, shall be validated to ensure that they function as intended. Functional tests shall be performed to verify the correct functioning of the software and hardware, and especially the interfaces. The system shall be checked (e.g. by entering correct and incorrect data, by simulating a loss of electrical power) to detect the availability, reliability, identity, accuracy and traceability of data or records.

5.3 Operational qualification (OQ)

5.3.1 Process parameters shall be challenged to assure that they will produce preformed sterile barrier systems, and sterile barrier systems, that meet all defined requirements under all anticipated conditions of manufacturing.

5.3.2 Preformed sterile barrier systems, and sterile barrier systems, shall be produced at both the upper and lower parameter limits, and shall exhibit the properties that meet predefined requirements. The following quality properties shall be considered.

a) For forming/assembly:

- sterile barrier system completely formed/assembled;
- product fits into the sterile barrier system;
- essential dimensions are met.

b) For sealing:

- intact seal for a specified seal width;
- channels or open seals;
- punctures or tears;
- material delamination or separation.

NOTE See EN 868-5:1999, 4.3.2 for an example of a seal width specification.

c) For other closure systems:

- continuous closure;
- punctures or tears;
- material delamination or separation.

5.4 Performance qualification (PQ)

5.4.1 The performance qualification shall demonstrate that the process will consistently produce acceptable preformed sterile barrier systems, and sterile barrier systems, under specified operating conditions.

5.4.2 Performance qualification shall include:

— the actual or simulated product;

— process parameters established in the operational qualification;

— verification of product/package requirements;

— assurance of process control and capability;

— process repeatability and reproducibility.

5.4.3 Challenges to the process shall include conditions expected to be encountered during manufacture.

NOTE These challenges can include, but are not limited to, machine set-up and change-over procedures; process start-up and restart procedures; power failure and variations, and multiple shifts, if applicable.

5.4.4 Challenges to the process shall include at least three production runs with adequate sampling to demonstrate variability within a run and reproducibility between different runs. The duration of a production run should account for process variables.

NOTE These variables include, but are not limited to, machine equilibrium, breaks and shift changes, normal starts and stops, and material lot-to-lot differences.

5.4.5 Documented procedures and specifications for the forming, sealing and assembly operations shall be established and incorporated into the performance qualification.

5.4.6 Essential process variables shall be monitored and recorded.

5.4.7 The process shall be under control and capable of consistently producing product according to predetermined requirements.

5.5 Formal approval of the process validation

5.5.1 Review and formal approval of the process validation shall be carried out and documented as a final step in the validation program.

5.5.2 The documentation shall summarize and reference all protocols and results, and state conclusions regarding the validation status of the process.

5.6 Process control and monitoring

5.6.1 Procedures shall be established to ensure that the packaging process is under control and within the established parameters during routine operation.

5.6.2 Critical process parameters shall be routinely monitored and documented.

5.7 Process changes and revalidation

5.7.1 Documents concerning packaging and sealing process shall be covered by a change-control procedure for documenting, verifying, and authorizing change.

5.7.2 Processes shall be revalidated if changes are made to the equipment, product, packaging materials or packaging process, which compromise the original validation and affect the sterility, safety, or efficacy of sterile medical devices.

NOTE The following is a list of changes which could affect the status of a validated process:

— raw material changes that would impact the process parameters;

— a new piece of equipment is installed;

— transfer of processes and/or equipment from one facility or location to another;

— sterilization-process changes;

— negative trends in quality or process control indicators.

5.7.3 The need for revalidation shall be evaluated and documented. If the situation does not require that all aspects of the original validation be repeated, this revalidation does not have to be as extensive as the initial validation.

5.7.4 Periodic revalidation or reviews should be considered since multiple minor changes could cumulatively affect the validation status of the process.

6 Packaging system assembly

6.1 The sterile barrier system shall be assembled under appropriate environmental conditions to minimize the risk posed by contaminants to the medical device.

6.2 The package system assembly process shall follow controlled labeling and processing procedures to prevent mislabeling.

NOTE Additional guidance can be found in DIN 58953-7 and DIN 58953-8.

6.3 Package systems shall be assembled and filled according to the instructions based on a validated process that assures sterilization in a defined sterilization process. These instructions should include configuration of contents and organizing inserts, total weight, inner wrapping, and absorbent materials.

7 Use of reusable sterile barrier systems

In addition to the requirements listed in Clause 6, instructions and restrictions for use as specified in 5.1.10 and 5.1.11 of ISO 11607-1:2006 shall be followed (e.g. assembly, disassembly, maintenance, repair, storage).

NOTE For additional guidance on reusable containers, see EN 868-8, DIN 58953-9, and AAMI/ANSI ST33. For additional guidance on reusable fabrics, see EN 13795-1 and ANSI/AAMI ST65.

8 Sterile fluid-path packaging

8.1 Assembly of sterile fluid-path components and closures shall meet the requirements of Clauses 5 and 6.

8.2 Medical devices labeled “sterile fluid path” shall maintain sterility of the fluid path by the construction of the device in combination with its closures.

NOTE 1 The requirements for microbial barrier properties and sterile barrier system integrity are provided in ISO 11607-1. The requirements apply to the device itself.

NOTE 2 For the purpose of interpreting the requirements of this part of ISO 11607, the device and its closures constitute the sterile barrier system.

Annex A
(informative)

Process development

Process development, while not a formal part of process validation, should be considered as an integral part of forming and sealing. Process development or process design requires an assessment to identify and evaluate critical parameters, along with their operating ranges, settings and tolerances.

A process assessment is conducted to establish appropriate and necessary upper and lower processing limits, as well as the expected normal operating conditions. These process limits should be sufficiently removed from failure or marginal conditions. One technique could be the creation of seal-strength curves with accompanying visual examples of seal results that could aid in the selection of an optimal process window.

Potential failure modes and action levels having the greatest impact on the process should be identified and addressed (failure mode and effects analysis, cause and effect analysis).

Statistically valid techniques, such as screening experiments and statistically designed experiments to optimize the process, should be used.

Essential processing parameters that are evaluated may include, but are not limited to:

— temperature;

— pressure/vacuum, including rate of change;

— dwell time (line speed);

— energy levels/frequency (radio frequency/ultrasonic);

— torque limits for lid/cap closure systems.

The selected essential parameters will be selected such that they will produce a process that is in control, and capable of yielding sterile barrier systems and packaging systems that meet predetermined design specifications.

Bibliography

[1] ISO 186:2002, *Paper and board — Sampling to determine average quality*

[2] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[3] ISO 9001:2000, *Quality management systems — Requirements*

[4] ISO/TS 11139:2006, *Sterilization of health care products — Vocabulary*

[5] ISO 13485:2003, *Medical devices — Quality management systems – Requirements for regulatory purposes*

[6] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

[7] EN 868-5:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods*

[8] EN 868-6:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation — Requirements and test methods*

[9] EN 868-8:1999, *Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming with EN 285 — Requirements and test methods*

[10] EN 13795-1:2002, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products*

[11] AAMI/ANSI ST33:1996, *Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities*

[12] ANSI/AAMI ST65:2000, *Processing of reusable surgical textiles for use in health care facilities*

[13] DIN 58953-7:2003, *Sterilization — Sterile supply — Part 7: Use of sterilization paper, nonwoven wrapping material, paper bags and heat and self-sealable pouches and reels*

[14] DIN 58953-8:2003, *Sterilization — Sterile supply — Part 8: Logistics of sterile medical devices*

[15] DIN 58953-9:2000, *Sterilization — Sterile supply — Part 9: Handling of sterilization containers*

[16] GHTF Study Group 3, *Process validation guidance for medical device manufacturers*

[17] *International Vocabulary of Basic and General Terms in Metrology*: 1993, BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML