INTERNATIONAL STANDARD

ISO 11607-1

Second edition
2019-02

AMENDMENT 1
2023-09

Packaging for terminally sterilized medical devices —

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

AMENDMENT 1: Application of risk management

Emballages des dispositifs médicaux stérilisés au stade terminal — Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

AMENDEMENT 1: Application de la gestion des risques

Reference number
ISO 11607-1:2019/Amd.1:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198*, Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11607 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Packaging for terminally sterilized medical devices —

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

AMENDMENT 1: Application of risk management

Clause 1, Scope

Delete the following text:

> It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized.

3.7

Replace term and definition entry with the following:

3.7
labelling
label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8]

Clause 3

Add the following term entries:

3.32
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 63: 2019, 3.2]

3.33
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

Note 2 to entry: "intended use" is used in the United States and "intended purpose" is used in the European Union. These terms have essentially the same meaning. Throughout this document, the term "intended use" is used.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — "intended purpose" was added to term, Note 2 to entry was added.]

3.34
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a process is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 have been deleted]

3.35
reasonably foreseeable misuse
use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 63:2019, 3.8]

3.36
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 63:2019, 3.10, modified — Note 1 to entry has been deleted]

4.2

Replace the text with the following:

4.2 Risk management

A risk management process conforming with the requirements of Annex F shall be implemented.

NOTE Annex F details requirements for the packaging risk management process, which is a subset of risk management for medical devices. Annex G provides background information on risk management for medical device packaging. Additional requirements for risk management of medical devices including sterile packaging can be specified by some regulatory jurisdictions. ISO 14971 covers application of risk management to medical devices and guidance on the application of ISO 14971 can be found in ISO/TR 24971.

4.4.3, NOTE

Replace with the following:

NOTE Annex B contains a list of test methods. Publication of a method by a standards body does not make it validated by the user of the test method.

6.1.1

Replace the text with the following:

6.1.1 The packaging system shall be designed to minimize the risks, as specified in Annex F, to the user and patient during intended use and/or reasonably foreseeable misuse.

NOTE See also 4.2 as well as Annex G for guidance on packaging risk management.

Bibliography

Add the following entries to the Bibliography:

[170] ISO/TR 24971, *Medical devices — Guidance on the application of ISO 14971*

[171] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[172] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

Annex F, Annex G

Add the following new Annexes F and G after Annex E.

Annex F
(normative)

Risk management

F.1 Risk management process

An ongoing risk management process applicable to packaging systems shall be established, implemented, documented and maintained. This process shall include:

a) identification of hazards and hazardous situations associated with the packaging system (see F.4,);

b) estimation (see F.5) and evaluation (see F.6) of the associated risks;

c) risk control (see F.7);

d) monitoring of the effectiveness of the risk control measures (see F.8).

F.2 Application of the risk management process

This process shall apply throughout the phases of design and development, validation, production and post-production of the packaging system. The following shall be included:

a) Design and development phase

— Packaging system design (see Clause 6).

NOTE G.2.7.4 provides guidance on general requirements for design and G.2.8.2 provides guidance on usability for aseptic presentation. Sealing and assembly process development is addressed in G.2.7.5 and ISO 11607-2.

b) Validation phase

— Performance and stability testing (see Clause 8 and G.2.8.3);

— Usability evaluation (see Clause 7 and G.2.8.2).

NOTE Process validation is addressed in G.2.8.4 and ISO 11607-2.

c) Production phase

— Packaging system changes (see Clause 9 and G.2.10).

NOTE Process control and monitoring, assembly, use of reusable sterile barrier systems, process changes and revalidation are addressed in ISO 11607-2 and G.2.9.

d) Post-production phase

— If post-production information is available on the performance of the packaging system, it shall be analysed to determine if risks are controlled appropriately or if unidentified hazards or hazardous situations are present. Consequent corrective and preventive actions shall be implemented as needed.

NOTE 1 The corrective and preventive actions can include redesign, additional controls or revalidation.

NOTE 2 This document does not include requirements for collecting post-production information or for reporting adverse events and field safety corrective actions to authorities or other related activities. This is typically established based on the requirements of the quality management system.

F.3 Risk management plan

F.3.1 General

A risk management plan shall be documented in accordance with the risk management process for each packaging system including at least the following:

— the scope of the planned risk management activities;

— criteria for risk acceptability;

— activities for verification of the implementation and effectiveness of risk control measures.

Risk management plans and related records and documentation for packaging systems may be combined with those for the medical device.

F.3.2 Criteria for risk acceptability

Criteria for risk acceptability shall be developed based on the following principles (see also G.2.6):

— align with the device to be packaged and its intended use;

— align with the intended use environment and related aseptic presentation;

— differentiate between essential design requirements for functionality (e.g. integrity) and lesser impact requirements (e.g. dimensional variance);

— consider the hazards defined in Table F.1, taking into account generally acknowledged state-of-the-art acceptance criteria as applicable (e.g. biocompatibility).

NOTE Local regulatory requirements can provide mandatory criteria for risk acceptability, or these criteria can be based on the generally accepted state-of- the-art.

F.3.3 Similar packaging systems

Risk management plans for similar packaging systems may be combined, in which case the rationale for these similarities shall be documented.

F.4 Specific hazards and hazardous situations to be addressed

For each of the hazards below, considering both normal and fault conditions, sequences of events shall be identified, and the resulting hazardous situations shall be evaluated:

— Microbial contamination;

— Chemical contamination;

— Adverse environmental, processing and use conditions;

— Misleading information.

Table F.1 provides examples of hazards and potential relevant factors.

Table F.1 — Hazards and potential relevant factors

Hazard	Potential relevant factors
Microbial contamination	Airborne, surface or material microbial contamination
Chemical contamination	Bio-incompatible or toxic materials or components, process residuals (e.g. EO residuals), incompatibility between device and packaging materials, sterilization process, labelling system
Adverse environmental, processing and use conditions	Exposure to incompatible temperature / pressure / humidity or moisture / UV lighting / shock / vibration (all storage and transport conditions)
	Inadequate or uncontrolled manufacturing process including the work environment
	Inappropriate sterilization method, inappropriate sterilization process cycle or sterilization process failure
	Use-related activities affecting patient safety including foreseeable misuse, such as human error
	Use-related activities affecting user safety, e.g. involved in transport and storage and dispensing (e.g. sharp edges, weight)
	Disposal factors: contamination, sharp edges, gas from incineration
Misleading information	Label design error
	Selection of label material and printing technology leading to incorrect ink transfer and poor legibility
	Mix-ups (e.g. incorrect label, wrong file or information, data)

NOTE For further guidance see G.2.2 on hazards to be addressed, G.2.3 on identification of sequences of events and G.2.4 on related hazardous situations. Table G.1 provides examples of relationship between hazards, foreseeable sequences of events and resulting hazardous situations.

F.5 Risk estimation

For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data.

Hazardous situations shall be assessed based on their probability of occurrence and the potential severity of related harm. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control.

The risk estimate may include detectability if the ability to detect the hazardous situation can be directly assessed.

NOTE See G.2.5 for guidance on risk estimation applied to medical packaging.

F.6 Risk evaluation

Under risk evaluation, estimated risks shall be compared against criteria for risk acceptability defined in the risk management plan to determine if the risk is acceptable or not and to identify risks to be controlled.

NOTE See G.2.6 for guidance on risk evaluation applied to medical packaging.

F.7 Risk control

Risks shall be controlled by implementing appropriate measures such that they are reduced to, or maintained within, levels as defined by the criteria for risk acceptability.

NOTE For further guidance on risk control see G.2.7.

Risk control in packaging system design for terminally sterilized medical devices shall be based on the following principles in the priority order listed:

a) Eliminate or reduce risks to an acceptable level through safe design. A packaging system (inclusive of sterile barrier system and protective packaging), is considered inherently safe by design for assurance of sterility when it meets the requirements below without additional measures.

   — Allow for sterilization (see 6.1.5).

   — Provide physical protection to maintain SBS integrity (see 6.1.3) for expected conditions and hazards during the specified processing, storage, handling, and distribution until that SBS is opened at the point of use (see 6.1.6).

   — Allow for the aseptic opening of the SBS and presentation of its contents (see 6.1.2).

   NOTE 1 The term “safe” in this context indicates the state where the risks from recognized hazardous situations have been reduced to an acceptable level (see ISO Guide 63:2019).

   NOTE 2 ISO 11607-1 provides the state-of-art approach to validate packaging for assurance of sterility, i.e. to reduce the risk of microbial contamination. In addition to the control of microbial contamination hazards for assurance of sterility, further hazards and risks must be considered where the state-of-art approach will be provided by other standards, e.g. ISO 10993-1 for chemical contamination and biocompatibility aspects.

b) Take adequate measures in relation to risks that cannot be eliminated, for example, shipping controls.

   NOTE An example of shipping controls would be the use of a temperature or humidity indicator for either a device or packaging, or both, that can be adversely affected by potential extreme temperature or high humidity exposures in transport.

c) Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users, for example, indication of opening location and sterile barrier system symbols.

F.8 Monitoring effectiveness of risk control measures

The implementation of risk control measures shall be verified.

If both design and manufacturing process outputs meet the acceptance criteria established in validation activities, the effectiveness of risk controls is then verified.

NOTE See G.2.8 for guidance on demonstration the effectiveness of the risk control measures and G.2.9 on process control and monitoring.