SLOVENSKI STANDARD
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Sterilizacija izdelkov za zdravstveno nego - Sevanje - 2. del: Določanje odmerka sterilizacije (ISO/DIS 11137-2:2026)

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO/DIS 11137-2:2026)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 2: Festlegung der Sterilisationsdosis (ISO/DIS 11137-2:2026)

Stérilisation des produits de santé - Irradiation - Partie 2: Établissement de la dose stérilisante (ISO/DIS 11137-2:2026)

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11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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ISO/DIS 11137-2

Sterilization of health care products — Radiation —

Part 2: Establishing the sterilization dose

Stérilisation des produits de santé — Irradiation —

Partie 2: Établissement de la dose stérilisante

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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 documents 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).

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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*.

This fourth edition cancels and replaces the third edition (ISO 11137-2:2013), which has been technically revised.

The main changes are as follows:

— Method VD_{max}^{SD} tables (i.e. 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy, and 35 kGy) from ISO 13004 were incorporated and Table 7 was added to describe the different sterilization doses and corresponding upper limit of average bioburden;

— Method VD_{max}^{SD} procedures were combined into one procedure rather than having separate procedures for each sterilization dose;

— VD_{max}^{SD} tables for 15 kGy, 17,5 kGy, 20 kGy, 22,5 kGy, and 25 kGy were all combined into one table, and for 27,5 kGy, 30 kGy, 32,5 kGy, and 35 kGy were all combined into a second table, and both updated tables were added into (normative) Annex A;

— VD_{max}^{SD} tables for dose augmentation values were also combined as described above and added into Annex A;

— VD_{max}^{SD} tables were truncated at average bioburden counts greater than 9,0 CFU to shorten the tables;

— Method 1 tables were moved to Annex A;

— information on maintaining product families, including product review considerations and product adoption from AAMI TIR35 was incorporated;

— information on bioburden limit of detection (LOD) and TNTC/spreaders was added in Clauses 5, 7, 9, 10, and Annex D;

— dose establishment method procedures (Method 1 and Method VD_{max}^{SD}) for a single batch were simplified to contain only the changes that need to be made to the multiple batch procedure when establishing dose for a single batch;

— information on a Modified Method 2 option from AAMI TIR40 was incorporated;

— information was added to allow continued use of the augmented verification and sterilization doses in Methods 1, 2A, or 2B;

— worked examples were moved to Annex B;

— guidance on sterilization dose audit failures was added in Annex C;

— guidance on bioburden alert and action levels was added in Annex E;

— guidance on sample size and microbiological controls was added in Annex F;

— guidance on selection of dose establishment method was added in Annex G;

— an example product adoption worksheet was added in Annex H.

A list of all parts in the ISO 11137 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.

Introduction

This part of ISO 11137 describes methods that can be used to establish the sterilization dose in accordance with one of the two approaches specified in ISO 11137-1:2025, 8.2. The methods used in these approaches are:

— dose setting to obtain a product-specific dose;

— dose substantiation to verify a preselected dose.

The basis of the dose setting methods described in this part of ISO 11137 (Methods 1 and 2) owe much to the ideas first propounded by Tallentire [18][19][20]. Subsequently, standardized protocols were developed (see References [8], [9]), which formed the basis of the dose setting methods detailed in the AAMI Recommended Practice for Sterilization by Gamma Radiation[1)] and ANSI/AAMI ST32[2)].

Methods 1 and 2 and the associated sterilization dose audit procedures use data derived from the inactivation of the microbial population in its natural state on product. The methods are based on a probability model for the inactivation of microbial populations. The probability model, as applied to bioburden made up of a mixture of various microbial species, assumes that each such species has its own unique D_{10} value. In the model, the probability that an item will possess a surviving microorganism after exposure to a given dose of radiation is defined in terms of the initial number of microorganisms on the item prior to irradiation and the D_{10} values of the microorganisms. The methods involve performance of tests of sterility on product items that have received doses of radiation lesser than the sterilization dose. The outcome of these tests is used to predict the dose needed to achieve a predetermined sterility assurance level (SAL).

A modification to Method 2 is provided that reduces the number of incremental doses needed to determine the minimum dose required to achieve a predetermined SAL. The Modified Method 2 can be employed at any time but is more successful when the product bioburden counts and resistance are low.

Methods 1 and 2 can also be used to substantiate any of the VD_{max}^{SD} doses if, on performing a dose setting exercise, the derived sterilization dose for the selected SAL is less than or equal to the selected sterilization dose. The basis of the method devised specifically for substantiation of 25 kGy, Method VD_{max}, was put forward by Kowalski and Tallentire.[14] Subsequent evaluations involving computational techniques demonstrated that the underlying principles were soundly based [13] and field trials confirmed that Method VD_{max}^{SD} is effective in substantiating a selected sterilization dose for a wide variety of products manufactured and assembled in different ways [16].

Method VD_{max}^{SD} is founded on dose setting Method 1 and, as such, it possesses the high level of conservativeness characteristic of Method 1. In a similar manner to the dose setting methods, it involves performance of tests of sterility on product items that have received a specified dose of radiation lesser than the sterilization dose. The outcomes of these tests are used to substantiate that the selected sterilization dose achieves the selected SAL.

To link the use of Method VD_{max} for the substantiation of a particular preselected sterilization dose, the numerical value of the latter, expressed in kiloGrays, is included as a superscript to the VD_{max} symbol. Thus, for substantiation of a sterilization dose of 25 kGy, the method is designated Method VD_{max}^{25}. Reference to the general term of the VD_{max} method but not to a selected sterilization dose is designated VD_{max}^{SD}.

This part of ISO 11137 also describes methods that can be used to carry out sterilization dose audits in accordance with ISO 11137-1:2025, Clause 12. Following establishment of the sterilization dose, sterilization dose audits are performed routinely to confirm that the sterilization dose continues to achieve the desired SAL.

1) Withdrawn.

2) Withdrawn.

Sterilization of health care products — Radiation —

Part 2: Establishing the sterilization dose

1 Scope

This document specifies methods for determining the minimum dose needed to achieve a specified requirement for sterility and methods to substantiate the use of a specified sterilization dose to achieve an SAL of 10^{-6}. This document also specifies methods of sterilization dose audit used to demonstrate the continued effectiveness of the sterilization dose.

This document defines product families for sterilization dose establishment and sterilization dose audit.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11137-1:2025, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11737-1:2018, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11137-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Terms and definitions

3.1.1
action level
value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018, 3.5]

3.1.2
alert level
value from monitoring providing early warning of deviation from specified conditions

[SOURCE: ISO 11139:2018, 3.11]

3.1.3
batch
defined quantity of a product intended or purported to be uniform in character and quality produced during a specified cycle of manufacture

[SOURCE: ISO 11139:2018, 3.21]

3.1.4
candidate product
product being examined for adoption into an existing product family

3.1.5
false positive
test result interpreted as growth arising from the product, or portions thereof, tested when either growth resulted from extraneous microbial contamination or turbidity occurred from interaction between the product, or portions thereof, and the test medium

3.1.6
fraction positive
quotient in which the number of positive tests of sterility is given by the numerator, and the number of tests performed is given by the denominator

[SOURCE: ISO 11139:2018, 3.122]

3.1.7
incremental dose
dose within a series of doses applied to a number of product, or portions thereof, and used in a dose setting method to obtain or confirm the sterilization dose

[SOURCE: ISO 11139:2018, 3.138]

3.1.8
packaging system
combination of a sterile barrier system and protective packaging

[SOURCE: ISO 11139:2018, 3.192]

3.1.9
positive test of sterility
test result for which there is detectable microbial growth from product, or portions thereof, subjected to a test of sterility

3.1.10
sample item portion
SIP
specified portion of a health care product that is tested

[SOURCE: ISO 11139:2018, 3.240]

3.1.11
standard distribution of resistances
SDR
reference set of resistances of microorganisms and corresponding probabilities of occurrence

[SOURCE: ISO 11139:2018, 3.263]

3.1.12
sterilization dose audit
exercise undertaken to confirm the appropriateness of an established sterilization dose

[SOURCE: ISO 11139:2018, 3.281]

3.2 Abbreviated terms

3.2.1
A
dose to adjust the median ffp dose downwards to the FFP dose

3.2.2
CD*
number of positive tests of sterility obtained from tests performed individually on 100 product items irradiated in a Method 2 verification dose experiment

3.2.3
d*
dose derived from an incremental dose experiment performed on product items drawn from a given production batch

3.2.4
D*
initial estimate of the dose to provide an SAL of 10^{-2} for the test items

Note 1 to entry: Generally, it is the median of the three d * values derived for a given product.

3.2.5
D**
final estimate of the dose to provide an SAL of 10^{-2} for the test items, which is used in the calculation of the sterilization dose

3.2.6
DD*
highest dose delivered in a Method 2 verification dose experiment

3.2.7
DS
estimate of the D_{10} value of microorganisms present on product after exposure to *DD**

3.2.8
***D* value**
D_{10} value
time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganism

Note 1 to entry: For the purposes of this part of ISO 11137, D_{10} applies to the radiation dose only and not to time.

[SOURCE: ISO 11139:2018, 3.75, modified — Note to entry has been added.]

3.2.9
first fraction positive dose
ffp
lowest dose of an incremental dose series, applied to product items drawn from a given production batch, at which at least one of the associated 20 tests of sterility is negative for growth

Note 1 to entry: Notation in lower case refers to results derived from product taken from a single batch.

3.2.10
First Fraction Positive dose
FFP
dose at which 19 positives out of the 20 tests of sterility are expected to occur, calculated by subtracting *A* from the median of three ffp doses

Note 1 to entry: Notation in upper case refers to results derived from product taken from all three batches.

3.2.11
First No Positive dose
FNP
estimate of the dose to provide an SAL of 10^{-2} for the test items, that is used in the calculation of *DS*

3.2.12
VD_{max}^{SD}
maximal verification dose for a given bioburden, consistent with the attainment of an SAL of 10^{-6} at a specified sterilization dose

4 Definition of product families for dose setting, dose substantiation and sterilization dose auditing

4.1 General

The establishment of a sterilization dose and the carrying out of sterilization dose audits are activities that are part of process definition and maintaining process effectiveness (see ISO 11137-1). For these activities, product may be grouped into families. Definition of product families is based principally on the numbers and types of microorganisms on or in product (the bioburden), the type being indicative of the microorganism's resistance to radiation (see ISO 11137-1:2025, A.7.2 and ISO 11737-1). Variables such as density and product configuration within its packaging system are not considered in the establishment of these product families because they are not factors that influence bioburden.

NOTE 1 In using product families for establishing the sterilization dose and for carrying out sterilization dose audits, it is important to be aware of the reduction in the ability to detect an inadvertent change within the manufacturing process that influences the effectiveness of sterilization. Furthermore, with the use of a single product to represent the product family, it is possible that changes that occur in other members of the product family will not be detected. The effect of a reduction on ability to detect changes in other members of the product family is understood and a plan for maintaining product families is developed and implemented before proceeding.

NOTE 2 The product families outlined in Clause 4 are based on their microbiological properties. In this document the concept of microbiological families is called product families.

4.2 Defining product families

4.2.1 The criteria for defining a product family shall be documented. Product shall be assessed against these criteria and the similarities between potential product family members considered. Consideration shall include all product- and sterile barrier system (SBS)-related variables that affect bioburden, including, but not limited to:

1. nature and sources of inputs, including, raw materials, components, and manufacturing process materials (e.g. water, cleaning solutions, machine fluids) and their ability to support microbial growth;
   a) product design and size as it relates to product bioburden;
   b) manufacturing processes, including level of automation versus manual operations and any washing or cleaning processes
   c) manufacturing equipment;
   d) manufacturing environment;
2. manufacturing location (see also 4.2.4).

The outcome of the assessment and considerations shall be recorded.

4.2.2 Product shall only be included in a product family if it is demonstrated that the product- and SBS-related variables (see 4.2.1) are similar and under control.

4.2.3 To include product within a product family, it shall be determined that bioburden comprises similar numbers and types of microorganisms.

4.2.4 Inclusion of product from more than one manufacturing location in a product family shall be specifically justified and recorded. In addition to all elements of 4.2.1, consideration shall be given to:

a) geographic or climatic differences, or both, between locations;

b) any differences in the control of the manufacturing processes or environment.

4.3 Designation of product to represent a product family

4.3.1 Product to represent a product family

4.3.1.1 The number and types of microorganisms on or in product shall be used as the basis for selecting product to represent a product family.

4.3.1.2 A product family shall be represented by one of the following:

a) the master product (see 4.3.2);

b) an equivalent product (see 4.3.3);

c) a simulated product (see 4.3.4).

4.3.1.3 A formal, documented assessment shall be undertaken to decide which of the three potential representative products in 4.3.1.2 is appropriate. In this assessment, consideration shall be given to the following:

a) number of microorganisms comprising the bioburden;

b) types of microorganisms comprising the bioburden;

c) environment in which the microorganisms occur;

d) size of product;

e) number of components;

f) complexity of product;

g) degree of automation during manufacture;

h) manufacturing environment;

i) SBS packaging process, materials, components and environment;

j) production frequency and volume of production.

4.3.2 Master product

A member of a product family shall only be considered the master product if assessment (see 4.3.1.3) indicates that the member presents a microbiological challenge to the sterilization process that is greater than that of all other product family members. The master product can have a different verification dose than other products that are given the same sterilization dose. In some situations, there can be several products within the product family, each of which could be considered as the master product. In such circumstances, any one of these products may be selected as the master product to represent the family, either

a) at random; or