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AMENDMENT 1
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Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization

AMENDMENT 1: Selection of items for dose setting

Stérilisation des dispositifs médicaux — Prescriptions pour la validation et le contrôle de routine — Stérilisation par irradiation

AMENDEMENT 1: Sélection des articles pour le choix de la dose

Reference number
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Foreword

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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 Amendment may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to International Standard ISO 11137:1995 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization

AMENDMENT 1: Selection of items for dose setting

Page 18, subclause B.3.1.2

Delete **B.3.1.2 Sample item portion for kits**, and replace with the following:

B.3.1.2 Selection of items for dose setting

A sterilization dose is established for a given product unit, where product unit is defined as a "health care product, collection of products or components within a primary package." This definition covers four situations:

a) an individual health care product within its primary package;

b) a set of components presented in a primary package, which are assembled at the point of use to form the health care product, together with accessories required to use the assembled product;

c) a number of identical health care products within a primary package; and

d) a kit comprising a variety of procedure-related health care products.

In all these situations, the objective is to establish the sterilization dose appropriate for the product unit.

The experiment to be carried out in performance of a dose-setting exercise, Method 1 or Method 2, is described in B.3.4. It is the outcome of this experiment that ultimately determines the choice of the sterilization dose. For the above situations a) through d), the nature of the item(s) employed in the dose-setting exercise will also influence the choice of sterilization dose; thus, a rationalized selection of the item(s) has to be made. As it is the product unit which undergoes sterilization treatment to produce an item that is sterile for use in patient care, it follows that each situation requires consideration of the manner of use of the health care product in clinical practice in order to decide the nature of the item to be employed in a dose-setting exercise. Guidance in this regard is given in Table B.26.

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Add the following new Table B.26:

Table B.26 — Selection of items for dose setting

Product unit	Item for bioburden estimation or incremental dose experiment	Item for verification experiment	Basis for choice of sterilization dose	Rationale
a) Individual health care product in its primary package	Individual health care product	Individual health care product	Individual health care product	Each health care product is used independently in clinical practice
b) Set of components in primary package	Combination of components	Combination of components	Combination of components	Components are assembled as a product and used together in clinical practice
c) Number of identical health care products in primary package	Single health care product taken from the primary package	Single health care product taken from the primary package	Single health care product taken from the primary package	Each health care product is used independently in clinical practice
d) Kit of procedure-related health care products	Each type of health care product	Each type of health care product	Health care product requiring the highest sterilization dose	Each health care product is used independently in clinical practice

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