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Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects

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English version

Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects

Stérilisation des dispostifs médicaux - Irradiation - Partie 3: Indications pour la dosimétrie

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 204.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN ISO 11137-3:2004) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This document is currently submitted to the parallel Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 11137-3:2004 has been approved by CEN as prEN ISO 11137-3:2004 without any modifications.

DRAFT INTERNATIONAL STANDARD ISO/DIS 11137-3

ISO/TC **198** Secretariat: **ANSI**

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Sterilization of health care products — Radiation —

Part 3: Guidance on dosimetric aspects

Stérilisation des produits de santé — Irradiation —

Partie 3: Guide sur les aspects dosimétriques

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ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

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 11137-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11137 consists of the following parts, under the general title *Sterilization of health care products — Radiation*:

— *Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Establishing the sterilization dose*

— *Part 3: Guidance on dosimetric aspects*

Introduction

An integral part of radiation sterilization is the ability to measure dose. The dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or international standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental factors on dosimeter response is known and taken into account.

Requirements in regard to dosimetry and dose measurement are given in ISO 11137-1 and ISO 11137-2. This part of ISO 11137 gives guidance to these requirements.

Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects

1 Scope

This International Standard gives guidance on the requirements relating to dosimetry and dose measurement in ISO 11137 parts 1 and 2. It applies to gamma irradiators using the radionuclides ^{60}Co and ^{137}Cs, and to irradiators using a beam from an electron or x-ray generator.

2 Normative references

The following standards contain provisions, which through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 11137-1 *Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions in ISO 11137-1 and ISO 11137-2, together with the following, apply.

3.1
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use

3.2
uncertainty
parameter, associated with the result of a measurement, that characterises the dispersion of values that could reasonably be attributed to the measurand

4 Measurement of dose

Measurement of absorbed dose in connection with the radiation sterilization of medical devices is expressed in terms of the absorbed dose in water. Dosimetry systems should be calibrated in terms of dose in water. In this International Standard, absorbed dose is referred to as dose.