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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 18280.2-2015

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

医疗保健产品灭菌 辐射 第2部分：建立灭菌剂量
(English Translation)

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Foreword

All technical content in this Part of GB 18280 is mandatory.

GB 18280 "Radiation Sterilization of health care products" is divided into the following sections.

--- GB 18280.1 Radiation Sterilization of health care products - Part 1. Development of medical equipment sterilization process, validation and routine control

System requirements;

--- GB 18280.2 Sterilization of health care products - Radiation - Part 2. Establish sterilization dose;

--- GB/T 18280.3 Radiation Sterilization of health care products - Part 3. dose measurement guide.

This is Part 2 GB 18280's.

This section drafted in accordance with GB/T 1.1-2009 given rules.

This portion instead of GB 18280-2000 "Sterilization of health care products Requirements for validation and routine control of radiation sterilization", and

GB 18280-2000 compared, this section developed from GB 18280-2000 Appendix B, the main technical changes as follows.

--- Increase the definition of the product family;

--- Refine the method to establish the dose, more detailed description of Tier 1 and Tier 2 applications;

--- Increased VDmax method.

This section uses the translation method identical with ISO 11137-2:2006 "Sterilization of health care products - Radiation - Part 2. Create sterilization dose".

The correspondence between the consistency of the international normative documents referenced in our country with the following documents.

--- GB/T 19973.1-2005 Sterilization of health care products - Microbiological methods - Part 1. The total number of microorganisms on the product assessment

Meter (ISO 11737-1.1994, IDT);

--- GB /learning methods - Part 2 T 19973.2-2005 microbial sterilization of medical devices. sterility test confirmed the sterilization process

(ISO 11737-2.1998, IDT).

This part is proposed by the China Food and Drug Administration.

This part of the National Standardization Technical Committee disinfection technology and equipment (SAC/TC200) centralized.

This section is drafted. Beijing Radiation Application Research Center, Shenzhen Jinpeng source of radiation Technology Co., Ltd., the State Food and Drug Administration

Administration of Guangzhou Medical Device Quality Supervision and Inspection Center.

introduction

GB 18280 This section describes two ways according to GB 18280.1-2015 8.2 given in any one establishment sterilization

Dose approach. These methods are.

- a) obtaining a method of setting product-specific dose;
- b) for a pre-selected or 15kGy do 25kGy dose confirmed.

Foundation set dose method described in this section is mainly Talentire first proposed (Talentire, 1973 [17];

Talentire, DwyerandLey, 1971 [18]; TalentireandKhan, 1978 [19]). Thereafter, the dosage form of the draft standard setting

Methodological basis through AAMI recommended gamma radiation sterilization practices (AAMI1984,1991 [4], [6]) to develop (Davisetal after thinning.,

1981 [8]; Davis, StrawdermanandWhitby, 1984 [9]).

Methods 1 and 2 and the relevant dose audit procedures use data derived from the natural state in the presence of microorganisms on products

body. Based on microbial population inactivation probability model. Since the bioburden of different microbial species composition, probabilistic model for each set

D10 value of individual species of microorganisms. In the model, when given with radiation dose, a product of the probability of a surviving microorganism is

Irradiated products before initial number of microorganisms and D10 values determined. The method comprises less than after the sterilization dose of radiation products, products that do not

Bacteria Test. Results of the tests used to predict the predetermined sterility assurance level of the dose required.

In the embodiment set dose trials, Tier 1 and Tier 2 can also be used to confirm the 25kGy to achieve a sterility assurance level of 10^{-6} .

Confirmed 25kGy method, namely. VDmax method by Kowalski and Talentire (1999) [14] development. Thereafter, the basic principles

Li made the assessment, including the application of computer presentations, and laid a good foundation (Kowalski for this method, Aoshuang and

Talentire, 2000 [13]), the field test demonstrated VDmax method for a variety of methods for producing the assembly out of the sterilization and products are all

Efficiency (Kowalski et al., 2002 [16]).

Use VDmax method confirmed 25kGy sterilization dose as a standard procedure has been published in the AAMI technical report "Health Care

Radiation sterilized product was confirmed as the sterilization dose VDmax 25kGy method "(AAMITIR27.2001) [5], this document sets

The main principle VDmax methods. VDmax based on dose setting Method 1, it has a high security. VDmax dose provided similar

Setting Method 1, including After the sterilization dose lower than the dose of radiation products, products for sterility test. The results of the test for confirming 25kGy

To achieve a sterility assurance level of 10^{-6} .

To represent VDmax proven method of pre-dose, the dose values will kGy units written in VDmax top right corner. Confirmed 25kGy,

He expressed as VDmax25.

Similarly, it was confirmed 15kGy expressed as VDmax15. Use VDmax15 test program is limited to the average bioburden ≤ 1.5 products, other

And VDmax25 same. Test results can be used to confirm 15kGy so that products meet a sterility assurance level of 10^{-6} .

This section also describes the basis for Chapter 12 GB 18280.1-2015 embodiment dose audit approach. After the establishment of the sterilization dose,

Sterilization dose audit is a routine conventional procedures to ensure continuous

sterilization dose needed to achieve a sterility assurance level.

Radiation Sterilization of health care products

Part 2. Establish sterilization dose

1 Scope

GB 18280 of the provisions of this part of the setting method and confirmed to meet the special requirements of sterile minimum dose of 25kGy or

15kGy as to achieve the 10^{-6} sterility assurance level (SAL) of the sterilization dose approach. This section also provides a dose audit approach to

As evidenced by sustained and effective sterilization dose.

This section defines for dose establishment and dose auditing product family.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein

Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 18280.1-2015 Radiation Sterilization of health care products - Part 1. Development of medical equipment sterilization process, validation and routine

Control requirements (ISO 11137-1:2006, IDT)

Sterilization Microbiological methods - Part 1 ISO 11737-1 medical devices. the total number of microorganisms on the product estimate

(Sterilization of medical devices - Microbiological methods - Part 1. Determination of a population of microorganisms on products)

Learn sterilization methods - Part 2 microorganisms ISO 11737-2 medical devices. sterility test confirmed the sterilization process

(Sterilization of medical devices - Microbiological methods - Part 2. Tests of sterility performed in the validation of a sterilization process)

3 acronyms, terms and definitions

GB 18280.1-2015 defined and the following abbreviations, terms and definitions apply to this document.