

ICS 11.080.01
CCS C 47



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

GB/T 18280.3-2015

**Sterilization of health care products -- Radiation -- Part 3:
Guidance on dosimeter aspects
(English Translation)**

Issued on: December 31, 2015

Implemented on: January 1, 2018

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China**

Table of Contents

Foreword...	3
Introduction...	5
1 Scope...	6
2 Normative references...	6
3 Terms and definitions...	6
4 Measurement of dose...	7
5 Selection and calibration of dosimetry systems...	7
6 Establishing the maximum acceptable dose...	8
7 Establishing the sterilization dose...	8
8 Installation qualification...	10
9 Operational qualification...	11
10 Performance qualification...	17
11 Routine monitoring and control...	21
Annex A (informative) Mathematical modelling...	23
Bibliography...	27

Foreword

GB 18280 consists of the following parts, under the general title Sterilization of health care products - Biological indicators.

- 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.

This Part is Part 3 of GB 18280.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part partly replaces GB 18280-2000 "Sterilization of health care products - Requirement for validation and routine control - Radiation sterilization". Compared with GB 18280-2000, this Part was developed from Annex C of GB 18280-2000, main technical content changes in this Part are as follows.

- ADD the introduction to sterilization dose;
- ADD the requirements for Installation Qualification, Operational Qualification and Performance Qualification;
- ADD the requirements for routine monitoring and control.

This Part uses translation method to identically adopt ISO 11137-3:2006 "Sterilization of health care products - Radiation - Part 3. Guidance on dosimetric aspects" (English version).

China's documents that are identical to the International documents normatively referenced in this Part are as follows.

- GB 18280.1-2015 Sterilization of health care products - Radiation - Part 1.

Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, IDT)

- GB 18280.2-2015 Sterilization of health care products - Radiation - Part 2.

Establishing the sterilization dose (ISO 11137-2:2006, IDT)

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing organizations of this document shall not be held responsible for identifying any or all such patent rights.

This Part was proposed by State Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee on Sterilization Techniques and Equipment of Standardization Administration of China (SAC/TC 200).

Drafting organizations of this Part. Beijing Radiation Application Research Center, Shenzhen JPY Ion-tech Co., Ltd., Guangzhou Medical Devices Quality Surveillance and Test Institute of State Food and Drug Administration.

Main drafters of this Part. Hu Jinhui, Chen Qiang, Wu Weirong, Zeng Mingsheng, Bao Yu and Hu Yang.

The previous edition of the standard replaced by this Part is as follow.

- GB 18280-2000.

Sterilization of health care products - Radiation -

Part 3. Guidance on dosimetric aspects

1 Scope

This Part of GB/T 18280 gives guidance on the requirements in GB 18280 parts 1 and

2 relating to dosimetry. Dosimetry procedures related to the development, validation

and routine control of a radiation sterilization process are described.

2 Normative references

The following referenced documents are indispensable for the application 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 Sterilization of health care products - Radiation - Part 1. Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2:2006 Sterilization of health care products - Radiation - Part 2.

Establishing the sterilization dose

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11137-1, ISO 11137-2 and 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.

[ISO/TS 11139:2005]

[19] SHARPE, P. and MILLER, A. Guidelines for the Calibration of Dosimeters for use in Radiation Processing. NPL Report CIRM 29, National Physical Laboratory, Teddington, TW11 0LW, UK (1999)

[20] Panel on Gamma and Electron Irradiation, Guidance Notes on the Dosimetric Aspects of Dose-setting Methods, The Panel on Gamma & Electron Irradiation,

212 Piccadilly, London, W1J 9HG, UK (1996)

[21] Panel on Gamma and Electron Irradiation, Discussion Paper on Uncertainties in Routine Dosimetry for Gamma and EB Plants, The Panel on Gamma & Electron Irradiation, 212 Piccadilly, London, W1J 9HG, UK (2002)

.....