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

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

(English Translation)

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1 Scope

1.1

This document specifies the requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

This document applies to irradiation facilities using the following radiation sources.

- a) Using radionuclides cobalt-60 or cesium-137;
- b) Electron beams emitted from electron accelerators;
- c) X-rays emitted from X-ray generators.

1.2

This document does not apply to the sterilization process of inactivated viruses or infectious spongiform encephalopathy pathogens such as scrapie, bovine spongiform encephalopathy, and

Creutzfeldt-Jakob disease.

NOTE: Relevant information can be found in GB/T 44353.1, GB/T 44353.2, YY/T 0771.3, ISO 13022, and ICH Q5A.

1.2.1 This document does not specify requirements for medical devices to be designated

"STERILE".

NOTE: For China's requirements for designating medical devices as "STERILE", refer to YY/T 0615.1.

1.2.2 This document does not specify a quality management system for controlling all stages of the medical device manufacturing process.

NOTE: This document does not require the establishment of a complete quality management system in manufacturing, but the elements that need to be controlled in the sterilization process within the quality management system shall refer to the applicable clauses in this document (see Clause 4). The application of the reference quality management system standard (see GB/T 42061) in the entire medical device manufacturing process, including sterilization, is permitted.

1.2.3 This document does not require the use of biological indicators in the validation and monitoring of radiation sterilization, nor does it require the use of products listed in the pharmacopoeia for test for sterility and release.

1.2.4 This document does not specify occupational safety requirements related to the design

and operation of irradiation plants.

NOTE: For Chinese occupational safety regulations related to radiation, refer to GB 10252, GB 18871, and HJ 979.

1.2.5 This document does not specify sterilization requirements for used and reprocessed

medical devices.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 19973.1 Sterilization of health care products - Microbiological methods - Part 1.

Determination of a population of microorganisms on products (GB/T 19973.1-2023, ISO 11737-1:2018, IDT)

GB/T 19973.2 Sterilization of health care products - Microbiological methods - Part 2. Tests of sterility performed in the definition, validation and maintenance of a sterilization process (GB/T

19973.2-2025, ISO 11737-2:2019, IDT)

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Dose

Absorbed Dose

The energy of ionizing radiation transmitted to a unit mass of a substance.

NOTE: The unit of absorbed dose is Gray (Gy), 1 Gy=1 J/kg (=100 rad).

[Source. ISO 11139:2018, 3.3, with modifications]

3.2 Bioburden

The total number of microorganisms surviving on or inside the surface of a product and/or a sterile barrier system.

[Source. ISO 11139:2018, 3.23]

3.3 Biological Indicator

[Source. ISO 11139:2018, 3.315]

4 General Requirements

4.1

The development, validation and routine control of a sterilization process are critical elements in the realization of health care products. To ensure the continued implementation of the requirements specified in this document, necessary processes need to be established, implemented, and maintained. Important processes related to the development, validation and routine control of a sterilization process include, but are not limited to.

--- control of documentation (including records);

- allocation of management responsibilities;
- provision of adequate resources, including qualified personnel and infrastructure;
- control of externally supplied products;
- product identification and traceability throughout the process;
- control of non-conforming products.

4.2 Calibration procedures for all equipment (including instruments used for testing purposes)

used to meet the requirements of this document shall be specified.

4.3 Dosimetry used for the development, validation and routine control of a sterilization process shall be traceable to national or international standards and shall have a known level of uncertainty.

NOTE: Dosimetry procedures are described in ISO/ASTM 52628.

5.1 Sterilizing Agent

5.1.1

The type of radiation used in the sterilization processing (e.g., gamma rays, electron beams, or X-rays) shall be specified.

5.1.2

For electron beams or X-rays, the energy level of the electron beam shall be specified.

The potential for induced radioactivity in the product and packaging system shall be assessed if any of the following conditions exist.

- The electron energy level exceeds 11 MeV;
- The electron energy level used to generate X-rays exceeds 7.5 MeV.

The results of the assessment and the basis for the decisions shall be documented.

NOTE: Further guidance is available in Appendix A.

5.2 Inactivation Efficacy

The application of radiation in the inactivation of microorganisms or in the sterilization processing is well documented in the literature. The aforementioned literature provides knowledge of how process variables affect microbial inactivation. This document does not require a comprehensive study involving microbial inactivation.