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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 16383-2014

Replacing GB 16383-1996

Quality control for the radiation sterilization of medical and hygienic products

医疗卫生用品辐射灭菌消毒质量控制

Issued on: December 22, 2014 **Implemented on: July 1, 2015**

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

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Foreword

Chapter 6 of this standard are recommendatory, the rest are mandatory provisions. This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard replaces GB 16383-1996 "medical and health supplies radiation sterilization quality control standards." This standard and GB 16383-1996 comparison, major technical changes are as follows:

--- Standard name from "medical and health supplies radiation sterilization quality control standards" to "medical and health supplies radiation sterilization QC";

--- A reference to the standard version has been updated and added GB 18280, GB 18871, "People's Republic of China Pharmacopoeia (two)" (2010 edition);

--- According to GB 18280 terms and definitions on the part of the sterilization dose is determined, remove the medical supplies production plant production requirements;

--- Remove the sterilization and disinfection dose and sterility assurance level requirements;

--- Increases may affect product quality should take corrective and preventive actions;

--- The "microbiological monitoring methods and requirements" as an independent Chapter 6, "Radiation product release requirements" as Chapter 7. Proposed for The quality of our country demands. This standard is proposed and managed by the National Health and Family Planning Commission People's Republic of China. This standard by the Jiangsu Provincial Disease Prevention and Control Center is responsible for drafting, Suzhou Municipal Center for Disease Control and Prevention, Chinese Center for Disease Control parameters Plus draft. The main drafters of this standard. Xu Yan, Tan Zhi, Chen Xueliang, Zhang stream wave, Zhang Jun, Lixin Wu, Sun Jun, Wu Xiaosong, Chen Wensen, Chenyue

Ying. This standard was first released in May 1996. Medical and health supplies radiation sterilization quality control

1 Scope

GB 16383 governs the sterilisation of medical and hygienic products by gamma or electron beam irradiation, a process whose defining difficulty is that the result cannot be inspected afterwards: the product looks identical whether the dose reached it or not. The standard therefore sets the quality control that stands in place of inspection. Clause 4 requires the product and its packaging to withstand the dose, the bioburden to be determined before irradiation, and the irradiation facility to hold a radiation safety licence and a radiation processing measurement permit under JJG 591, GB 18871 and GB 18280, with the sterilization dose established under GB 18280. Clause 5 covers the dosimetry: calibrated dosimeters, working dosimeters at fixed routine positions, a dose distribution map for every loading pattern, and a dose uniformity ratio Dmax/Dmin below 1.5. Clause 6 requires ten samples per batch for the initial bacterial contamination and ten biological indicators at the minimum dose position, tested for sterility against the Chinese Pharmacopoeia. Clause 7 governs release - including the case where the dose was right but part of the batch arrived with damaged packaging - and clause 8 the labelling, the certificate, the segregation of treated and untreated stock and the scrapping of anything whose seal has failed. Annex A, normative, gives the pour-plate and membrane-filtration methods for the bioburden count. Issued on 22 December 2014, in force since 1 July 2015, replacing GB 16383-1996. This page is published from the official record of the standard and from its published table of contents. The full clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies the medical and health supplies radiation sterilization and disinfection of terms and definitions, radiation sterilization and disinfection requirements, the product of radiation treatment to Requirements, microbiological monitoring methods and requirements, requirements and release management requirements radiation after radiation products. This standard applies to all units to carry out radiation sterilization and disinfection.

2 Normative references

The following documents for the application of this document is essential. Any application document dated, dated version only suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 18280 Sterilization of health care products Requirements for validation and routine control of radiation sterilization

GB 18871 ionizing radiation protection and safety of radiation sources basic standards

JJG591 gamma-ray radiation (Radiation Processing) People's Republic of China Pharmacopoeia (two) (2010 Edition)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Sterility assurance level Sterilizationassurancelevel; SAL There is a single probability of viable microorganisms on the product after sterilization, usually expressed as a 10-n.

3.2 D value Dvalue In setting the exposure conditions, required to kill 90% of the total absorbed dose of radiation specific test organisms.

3.3 Bioburden bioburden A product or activity on the total number of microorganisms present in a package.

3.4 Biological indicators biologicalindicator It has a definite resistance to specific sterilization or disinfection procedures for monitoring the use of sterilization effect of microbiological testing equipment.

3.5 Absorbed dose absorbeddose Unit mass of the material of the magnitude of the energy absorbed.

Note. The unit of absorbed dose is Gy (Gy), 1Gy = 1J/kg.

3.6 Absorbed dose unevenness unevenress Radiation product box, different parts of the measured maximum absorbed dose (Dmax) divided by the minimum absorbed dose (Dmin) of the provider, see equation (1). U = Dmax Dmin (1) Where. Dmax

--- the maximum absorbed dose; Dmin

--- minimum absorbed dose.

3.7 Dosimeter dosimeter Dosimeter One kind can measure the radiation dose received by the instrument in time to be determined.

3.8 Working dosimeter workingdosemeter After standard dosimeter calibrated for calibration of radiation field and dose rate measurement of absorbed dose products for regular dose monitoring of agent Meter.

3.9 Sterilization dose sterilizationdose To achieve a specified sterilization requirements of the minimum dose required.

4.1 In the medical and health supplies radiation sterilization before requirements

4.1.1 medical and health supplies and packaging materials should be resistant to radiation sterilization dose of material. Bioburden

4.1.2 medical supplies should be carried out testing to ensure the effectiveness of the use

of radiation sterilization.

4.1.3 respect for anomalies that may affect product quality, technology, production and other corrective actions should occur.

4.1.4 should take appropriate precautions to potential hazards that may affect the product quality of technology, production environment.

4.2 pairs of radiation sterilization and disinfection unit requirements

4.2.1 radiation sterilization and disinfection unit of radiation facilities installation, identification, operation, officers should reach JJG591, GB 18871 and GB 18280 Requirements, and shall obtain radiation safety license and the state department issued a qualified radiation processing measurement permits; the operator should go through training Training, technology assessment certificate holders posts.

4.2.2 radiation sterilization and disinfection unit should have sufficient detection capability to radiation sterilization bioburden and sterility testing of products to be based on, Establish and validate the sterilization dose, to ensure the effectiveness of radiation processing.

4.2.3 radiation sterilization and disinfection unit for abnormal situation should be the appropriate corrective and preventive actions.

4.3 to establish the sterilization dose Conducted in accordance with GB 18280 requirements.

5.1 Absorbed dose measurement

5.1.1 radiation sterilization unit used dosimeter must be regularly calibrated.

5.1.2 Working dosimeters should be placed on pre-determined point of the conventional dose, after radiation dose measurement, recording and analysis of results.

5.2 Product radiation sterilization and disinfection

5.2.1 The product packaging size, density and distribution of the product in the package, the product of the radiation container loading pattern detailed description.

5.2.2 Each should do to be radiation dose distribution map to determine the maximum dose and minimum dose position and size, and to determine the maximum dose Relationship between dose and conventional dose minimum dose point.

5.2.3 radiation to be irradiated product should be evenly filled container, unevenness absorbed dose should be less than 1.5.

6 microbiological monitoring methods and requirements

6.1 The initial detection of bacterial contamination Each production batch of at least 10 randomly selected samples in accordance with the requirements of GB 18280 of initial