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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

WS 310.3-2009

Replacing WS 310.3-2009

Central sterile supply department (CSSD). Part 3: Surveillance standard for cleaning; disinfection and sterilization

(English Translation)

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Foreword

This section 4.2.1.3, 4.2.2.2.1, 4.4.1.7, 4.4.4.3.2 for the recommended terms, the rest are mandatory terms.

This standard is formulated in accordance with Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases and Measures for the Management of Nosocomial Infections.

WS 310 "Hospital Disinfection Supply Center" is from the point of view of hospital infection prevention and control of medical equipment, hospital disinfection supply center the management, operation, monitoring standards to be regulated by the following three components.

--- Part 1. Management practices;

--- Part 2. Cleaning and disinfection and sterilization techniques and specifications;

--- Part 3. Cleaning and disinfection and sterilization effect monitoring standards.

This part is the third part of WS 310.

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

This section instead of WS 310.3-2009. In addition to editorial changes outside the main technical changes are as follows.

--- In the scope of application, delete the "disinfection of the supply has not yet implemented centralized management of hospitals, the Department of Surgery (room) disinfection supply workers should be implemented this standard "and" have taken centralized sewage treatment of other medical institutions can refer to the use of "requirements;

--- In the normative references, an increase of WS/T 367 "medical institutions disinfection technical specifications" and GB/T 30690 "small pressure Steam sterilizer sterilization effect monitoring methods and evaluation requirements ";

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--- Adjust the terms and definitions A0 value and lumen devices to WS 310.2; increase the definition of overhaul (see 3.4);

--- Modify the monitoring materials, homemade test standard package requirements (see 4.1.3);

--- Increasing the pressure steam sterilizer temperature, pressure and time of detection requirements [see 4.1.5.b)];

--- Increasing the quality of cleaning can be carried out regularly quantitative requirements (see 4.2.1.3);

--- Increase the use of specific sterilization procedures for sterilization quality monitoring requirements (see 4.4.1.6); increased the number of foreign medical devices, implanted Requirements for Sterilization Parameters and Validity Tests for First Sterilization of Oversized Overweight Packs (See 4.4.1.8);

--- Increasing the pressure steam sterilization annual monitoring temperature, pressure and time and other parameters of the requirements (see 4.4.2.1.2);

--- Increasing the use of information systems after surgical equipment package marking requirements [see 5.4.c)]; increased regular monitoring data Summary analysis, continuous improvement requirements (see 5.6);

--- Added Appendix D Hydrogen Peroxide low temperature plasma sterilization biological monitoring methods and Appendix E low temperature steam formaldehyde sterilization organisms Monitoring method.

This section mainly drafted by. Peking University First Hospital, National Institute of Health and Family Planning and Management Hospital, Peking Union Medical College Hospital, China disease Center for Disease Control and Prevention Environment and Health Product Safety, Shanghai Ruijin Hospital, Guangzhou First People's Hospital, Nanjing, Jiangsu Province Health Bureau, Zhejiang Provincial Center for Disease Control and Prevention, PLA General Hospital, West China Hospital of Sichuan University, Run Shaw Hospital of Zhejiang University, Peking University Third Hospital, Peking University Stomatological Hospital, TEDA International Cardiovascular Hospital, Zhongshan City, Guangdong Province, Xiaolan People's Hospital, Heilongjiang Center for Disease Control and Prevention, North Beijing Jishuitan Hospital, Beijing Municipal Health Authority, Beijing Chaoyang Hospital.

1 Scope

WS 310 provisions of this section of the hospital disinfection Supply Center (centralsterilesupplydepartment, CSSD) disinfection and sterilization Requirements, methods for monitoring of effects, records of quality control processes and traceability requirements.

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This section applies to hospitals and hospitals to provide disinfection and sterilization services disinfection services.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB 15982 hospital disinfection health standards GB/T 20367 health care products Sterilization Health care institutions to confirm the wet heat sterilization and conventional control requirements GB/T 30690 small pressure steam sterilizer sterilization effect monitoring methods and evaluation requirements WS 310.1 Hospital Disinfection Supply Center - Part 1. Management Practices WS 310.2 Hospital Disinfection Supply Center - Part 2. Code of Practice for Cleaning, Disinfection and Sterilization WS/T 367 medical institutions disinfection specifications

3 Terms and definitions

WS 310.1, WS 310.2 defined by the following terms and definitions apply to this document.

Traceability the key elements that affect the sterilization process and results are recorded, saved for future reference, and traceable.

Sterilization process validation device processchalengedevice; PCD A device that has specific resistance to the sterilization process to evaluate the effectiveness of the sterilization process.

Cleaning effect test object testsoil Used to test the cleaning effect of the product.

Overhaul majorrepair Maintenance beyond the scope of routine maintenance of this equipment, which significantly affects the performance of the equipment.

Example 1. Pressure Steam Sterilizer Overhaul If the vacuum pump is replaced, a valve connected to the chamber, a large steam supply pipe, a control system, or the like.

Example 2. Cleaning Disinfection Overhaul such as changing water pump, cleaning agent supply system, heating system, control system, etc.

Small steam sterilizer smalsteamsterilizer Pressure steam sterilizer less than 60L in volume.

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