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Application specification for hospital cleanrooms and associated controlled environments - Part 1: General guidelines

医院洁净室及相关受控环境应用规范 第1部分：总则

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Foreword

GB/T 33556 Application Specification for Hospital Cleanrooms and Associated Controlled Environment can be divided into the following 4 parts.

- Part 1. General Guidelines;

- Part 2. Operating Room, Hematopoietic Stem Cell Transplantation Room, Burn Ward, etc.;

- Part 3. Reproduction Center, Cell Therapy and the Like Micro Operation Environment;

- Part 4. Others.

This Part belongs to Part 1 of GB/T 33556.

This Part was drafted as per the rules specified in GB/T 1.1-2009.

This Part was proposed by and under the jurisdiction of National Technical Committee for Standardization of Cleanrooms and Associated Controlled Environment.

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Introduction

Hospital cleanroom is one of the auxiliary measures to control the hospital infection. In 1961, Sir John Charnley (1911-1982) known as "Father of Hip Arthroplasty" in the British Wrightington Hospital pioneered to, by cleaning the air method, improve the operating room environment; so that reduce surgical infection. However, the literature on relationship between air environment and surgical infection rate that had the clinical significance of medical statistics and was widely cited was published by LidewellOM et al. in 1987, the title of such literature is of "Multiple Studies on Ultra Clean Air and Antibiotics Used to Prevent Postoperative Infection in 8052 Cases of Joint Replacement Surgery"; such study recognized, to a certain extent, the role of ultra clean air.

Internationally, for the role of the hospital cleanroom and associated controlled environment in reducing the rate of infection, the medical field and engineering personnel in the cleanroom and associated controlled environment had their own opinions. The medical field has long been skeptical about the effectiveness of clean operating room. In recent year, the international medical field proposed more specific doubts on the laminar flow clean operating room based on statistical analysis on a large number of clinical case practice. The introduction of the Russian Federation Standard GOSTR 52539-2006 General Requirements for Air Cleanliness in Hospital prepared by Russian Association of Micro-Contamination Control Engineers clearly states that the cleanroom ventilation, air conditioning system and equipment can't replace the traditional hospital bacterial control measures, but can only supplement it.

Human's cognition on medical infection is still in the process of exploration. In the air attached to the dust of microorganisms (In the relevant information at home and abroad, the literature has not been found on the exact relationship between the number of dust and microorganisms. Obviously, animals and plants are more likely to scatter off the fine dust containing microorganisms, such as pollen, body debris, etc.) have been recognized at home and abroad one of the objects of prevention; while purifying the air in the medical space has become one of the measures to prevent the medical infection.

China's national serial standards of GB/T 25915 Cleanrooms and Associated Controlled

Environment equivalently adopting ISO 14644 internals serial standards drew lessons on the international counterparts' systematic concepts in each links such as test, design, construction, start operation, etc. To give full play to the role of the hospital cleanroom, and meet the use requirements, every detail in the operation can't be ignored.

The energy consumption for the air conditioning system and ventilation in the hospital cleanroom and associated controlled environment is about 5tims ~ 10times of that in the high-grade hotel with the same area. Reasonably determining the matching among Application Specification for Hospital Cleanrooms and Associated Controlled Environment - Part 1. General Guidelines

1 Scope

This Part of GB/T 33556 specifies the specifications on the verification, operation management, maintenance, and etc. of hospital cleanroom and associated controlled environment.

This Part is applicable to the hospital cleanroom and associated controlled environment like clean operating room, hematopoietic stem cell transplantation room, reproduction center, burn ward, ICU ward, intravenous infusion preparation center.

2 Normative References

GB 15982

GB 19083-2010

GB/T 25915.2-2010

2 Specifications for Testing and Monitoring to Prove Continued Compliance with

GB/T 25915.1 GB/T 25915.3-2010 Cleanrooms and Associated Controlled Environments - Part

3 Test Methods

GB/T 25915.4 Cleanrooms and Associated Controlled Environments - Part 4.

Design, Construction and Start-Up GB/T 25916.1 Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1. General Principles and Methods [GB 50333-2013, definition 2.0.13]

3.6 Operational

Facilities are operated in the specified state; there is specified personnel present; and work

in an agreed state.

3.7 Installation acceptance inspection

Facilities have been built; under the as-built condition, confirm whether the performance parameters of facilities in the cleanroom and associated controlled environment meet the requirements of design.

3.8 Function acceptance inspection

Under the at-rest condition, confirm whether the performance of facilities in the cleanroom and associated controlled environment satisfies (continues to meet) the requirements of design.

3.9 Operational evaluation

Under the specified operational condition, conform the compliance of performance parameters of facilities in cleanroom and associated controlled environment.

4.1.1.1 When designing new hospital buildings of cleanroom and associated

controlled environment, it shall be performed after assessing the rationality of controlled environment, overall layout, etc.

4.1.1.2 Before constructing the cleanroom and associated controlled environment

within the existing building, assess the rationality of the following items like controlled environment function, requirements, classification of cleanliness, overall layout, indoor... .....