NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 33556.1-2017

Application Specification for Hospital Cleanrooms and Associated Controlled Environment - Part 1: General Guidelines

Issued on: May 12, 2017 **Implemented on: December 1, 2017**

Issued by: AQSIQ; SAC

Table of Contents

Foreword... 3
Introduction... 4
1 Scope... 6
2 Normative References... 6
3 Terms and Definitions... 7
4 Requirements... 8

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.

Drafting organizations of this Part. Success Way Clean Technology Co., Ltd., Tianjin Longchuan Purifying Engineering Co., Ltd., China Association for Standardization, PLA General Hospital, Air Force General Hospital, Peking University Third Hospital, Peking Union Medical College Hospital of Chinese Academy of Medical Science, China IPPR International Engineering Co., Ltd., Alliance Contracting Co., Ltd., Institute of Medical Equipment Academy of Military Medical Science, TINAVI Medical Technologies Co., Ltd., Shenzhen Lifeng Cleanroom Technologies Co., Ltd., YANTAIR Co., Ltd., Jiangsu

Suzhou Purification Science and Technology Co., Ltd., Research Institute of Chemical Defense, Guangzhou Clima Air Purity Equipment Co., Ltd., Shenzhen Jilong Contamination Control Technology Co., Ltd., Beijing North Tianyu Architectural Decoration Co., Ltd., Wuxi Hanjia Medical Science & Technology Co., Ltd., Shenzhen Weida Medical System Engineering Co., Ltd., and Beijing Huayee Shenzhou Technology Co., Ltd.

Chief drafting staffs of this Part. Yang Ziqiang, Cao Jingui, Yin Xiaodong, Xu Huoju, Jiang Weikang, Zhang Lihai, Zhao Ameng, Huang Jihui, Yu Ziqiang, Tu You, Lin Xiangyang, He Li, Guo Li, Zhou Hengjin, Ma Dong, Li Zhiping, Yang Xiaobing, Chen Hanqing, Zhang Xiaodong, Bing Shaotong, Pan Xuegang, Jiang Haoxia, Tong Guangcai, and Hou Bin.

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

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB 15982 Hygienic Standard for Disinfection in Hospitals

GB 19083-2010 Technical Requirements for Protective Face Mask for Medical Use

GB/T 25915.2-2010 Cleanrooms and Associated Controlled Environments - Part

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.