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**General requirements for low temperature medical cold
store**

低温医用冷库通用技术要求

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Table of Contents

Foreword.....	3
1 Scope	4
2 Normative references.....	4
3 Terms and definitions.....	4
4 Basic requirements	5
5 Environmental and hygiene requirements	7
6 Safety requirements	8
7 Component requirements	8
8 Assembly requirements	9
9 Tests.....	9

Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2020 “Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents”.

Attention is drawn to the possibility that some of the elements of this Standard may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by China National Light Industry Federation.

This Standard shall be under the jurisdiction of National Technical Committee on Refrigeration of Standardization Administration of China (SAC/TC 119).

The drafting organizations of this Standard: Zhengzhou Kaixue Cold Chain Co., Ltd., Henan Provincial Center for Disease Control and Prevention, China Refrigeration Society, Institute of Physics and Chemistry, Chinese Academy of Sciences, Chinese Center for Disease Control and Prevention, Tianjin National Biological Protection Equipment Engineering Technology Research Center, Qingdao Haier Biomedical Co., Ltd.

Main drafters of this Standard: Dai Canli, Chen Yong, Gong Maoqiong, Wang Dan, Yan Huili, Liu Zhanjie, Yin Congxu, Feng Renjun, Wei Qiang, Qi Jiancheng.

General requirements for low temperature medical cold store

1 Scope

This Standard specifies the basic requirements, environmental and hygiene requirements, safety requirements, component requirements, assembly requirements and test methods for low temperature medical cold store.

The Standard is applicable to low temperature non-walk-in indoor prefabricated cold store for medical samples, biological agents, biological samples, of which the nominal volume is not more than 300m³, that is of mechanical refrigeration (hereinafter referred to as the low temperature medical cold store). The low temperature cold store for storing other special goods shall be implemented by reference.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 3096, *Environmental quality standard for noise*

GB/T 3785.1, *Electroacoustics - Sound level meters - Part 1: Specifications*

GB/T 9237, *Refrigerating systems and heat pumps - Safety and environmental requirements*

GB/T 18883, *Indoor air quality standards*

JB/T 6527, *The sandwich panel use for prefab cold store*

SBJ 14, *Code for installation and acceptance of refrigerating system with HCFC, HFC refrigerant*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 low temperature medical cold store

The non-walk-in indoor prefabricated cold store that the temperature range is $-186^{\circ}\text{C}\sim-40^{\circ}\text{C}$, that is used for low temperature test or low temperature storage, preservation of medical samples, biological agents, biological samples and special materials.

3.2 biological sample

Any substance obtained or derived from living organisms such as humans, animals, plants, microorganisms or non-animal/vegetable multicellular organisms such as brown algae and fungi.

3.3 non walk-in cold store

The cold store that no personnel is allowed in daily operation.

3.4 cooling-down time

Under the specified test conditions, the time required for the average temperature of each measurement point to reach the specified temperature when the low temperature medical cold store runs continuously under no-load condition.

4 Basic requirements

4.1 The low temperature medical cold store shall be manufactured and installed in accordance with this document and the drawings and technical documents of the professional designer. Special requirements shall be required in the contract or agreement. Supplementary provisions or explanations shall be made in the corresponding technical documents.

4.2 Environmental protection materials shall be adopted for the used envelope structure, thermal insulation materials and refrigeration system thermal insulation materials.

4.3 The low temperature medical cold store shall have independent double door lock storage door and equipment with double management function.

4.4 The low temperature medical cold store shall have a backup refrigeration device, so as to ensure that the storage temperature requirements are met under the condition of refrigeration system failure.

4.5 The low temperature medical cold store shall have all-weather, full-time remote monitoring and information alarm functions. It shall have control and rights management functions.

4.6 The storage temperature shall meet the requirements of Table 1.

4.12 The resolution of the pressure measuring device shall not be greater than 0.01MPa. The measurement error shall not be greater than 0.01MPa.

4.13 The temperature and pressure data of the refrigeration system shall have a display function. It shall be automated and exportable. The recording interval can be set from 1min ~ 30min. The data retention period shall not be less than 36 months.

4.14 The temperature in the store is higher than the upper limit or lower than the lower limit set alarm temperature. Refrigeration system pressure is higher than the upper limit or lower than the lower limit set alarm pressure. All shall have an alarm function. Alarm parameters can be manually operated on site or set remotely. The alarm mode is displayed by sound and light alarm or warning. When alarming, it shall have the function of automatically sending alarm information.

4.15 The low temperature medical cold store shall have management functions such as sample storage, retrieval and statistics.

4.16 The low temperature medical cold store for important medical samples, biological preparations, biological samples shall be equipped with a temperature monitoring system.

5 Environmental and hygiene requirements

5.1 According to the requirements of GB/T 18883, when the low temperature medical cold store is installed indoors, the ambient temperature shall be controlled at 16°C~28°C; the relative humidity of the environment shall be controlled at 30%~80%; the fresh air volume shall not be less than 30m³/(h·person). For the storage of biological products with special requirements, they shall also meet their special requirements, such as biological (total number of bacteria), cleanliness, ultraviolet disinfection.

5.2 The illumination of the core work area of the work site outside the store shall not be less than 350lx. The illumination of other areas shall not be less than 200lx. Waterproof, energy-saving lighting shall be used. The workplace shall avoid excessive light and light reflections. Configure an emergency lighting system with a lighting time of not less than 30min.

NOTE: The above-mentioned illuminance is the measured value at a height of 1m from the ground.

5.3 The impact of noise during operation on the surrounding environment shall comply with the provisions of GB 3096.

5.4 The low temperature medical cold store shall have anti-vibration, moisture-proof and rodent-proof facilities. The facilities shall be regularly cleaned, disinfected and maintained.

7.4.2 Electrical components shall have product certification.

8 Assembly requirements

8.1 When the store body is an assembled structure, each side, top and bottom surface shall be composed of heat-insulating sandwich panels. It can be integrally formed or installed on site.

8.2 The dislocation between the plates at the joints of the enclosure structure shall not be greater than 2mm. The difference between the diagonals of the surfaces shall not be greater than 1.5/1000 of their theoretical value.

8.3 The sealing strip of the low temperature medical cold store door shall be close to the surrounding of the door frame. The sealing performance shall be good.

8.4 The joints of the inner tank of the low temperature medical cold store shall be sealed evenly, continuously and uninterruptedly with a low-temperature-resistant sealant.

8.5 The gap fastening material of the low temperature medical cold store shall be made of the same expansion coefficient material as the inner tank, so as to ensure the same low temperature deformation coefficient.

8.6 Electrical switches, buttons, meters and indicator lights shall be firmly installed and meet the requirements of IEC 61010-1. The operation of all switches and buttons shall be sensitive, precise and reliable.

8.7 Refrigeration system assembly shall meet the requirements of SBJ 14.

8.8 When pipes and cables pass through the storage body, anti-cold bridges and sealing treatments shall be used. The treatment surface shall be smooth, firm and safe.

8.9 The refrigeration unit shall have safety protection devices and control devices to maintain the normal operation of the low temperature medical cold store.

9 Tests

9.1 Test conditions

9.1.1 Test environment

The low temperature medical cold store shall be suitable for one or more of the temperature bands shown in Table 3.

9.2 Test methods

9.2.1 General requirements

Visually inspect the cold store components and assembly quality.

9.2.2 Storage temperature

Cool down according to the test conditions specified in 9.1. When the operation of the low temperature medical cold store reaches a stable operation state, and the operation is stable for at least 24h, for multiple defrosts, the whole test operation cycle is the time of the integral multiple of the defrost interval closest to 24h. Record the temperature of each measurement point in the store.

9.2.3 No-load cooling-down time

According to the environment specified in 9.1, close the door of the low temperature medical cold store. Adjust the thermostat to the required set position for the storage temperature. Turn on the refrigeration unit. Test the time when the temperature in the test room reaches the storage temperature.

9.2.4 Condensation

Continue to carry out after the end of the storage temperature test in 9.2.2. Other conditions for the operation of the low temperature medical cold store are the same as the storage temperature test. The stable operation time shall be at least 4h. Record the ambient temperature, ambient humidity, temperature of each measuring point and condensation.

9.2.5 Defrost performance

After the low temperature medical cold store reaches a stable operating state, observe whether it can resume normal operation after the defrosting process and the temperature change in the store.

9.2.6 Noise testing

Measure according to GB 3096 requirements.

9.2.7 Safety test

Carry out in accordance with the provisions of IEC 61010-1.

9.2.8 Cold store components

Use visual inspection and hand inspection.

9.2.9 Store body structure

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