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Mobile laboratories - General requirements for biosafety

移动式实验室 生物安全要求

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Mobile laboratories - General requirements for biosafety

1 Scope

This Standard specifies the basic requirements for the facilities, equipment and safety management of the level 1, level 2 and level 3 biosafety protection level mobile laboratories, excluding the requirements for mobile biosafety level 4 laboratories and biosafety level 3 laboratories with open or semi-open animal rearing.

Chapter 6, 7.1 and 7.2 are the basic requirements for mobile laboratory biosafety protection facilities and equipment. When necessary, they are applicable to mobile laboratories with higher protection levels.

For laboratory activities related to the breeding of infected animals, this Standard specifies the basic requirements for animal breeding facilities and environments in mobile laboratories. When necessary, 7.3 is applicable to the animal biosafety mobile laboratory of the corresponding protection level.

This Standard applies to mobile laboratories involved in the operation of biological factors.

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 14925-2010, Laboratory animal - Requirements of environment and housing facilities

GB 19489-2008, Laboratories - General Requirements for Biosafety

3 Terms and definitions

The following terms and definitions are applicable to this document.

3.1

mobile laboratory

Laboratory that can be used in different locations.

3.2

directional airflow

Airflow that is directionally controlled.

3.3

primary barrier

A physical barrier or isolation between the operator and the action object.

Note: Personal protective equipment is also considered a primary barrier. When it is not specified in this Standard, the primary barrier refers to protective equipment such as biological safety cabinet or isolator.

3.4

secondary barrier

A physical barrier or isolation between the public environment and the action object.

Note: The enclosure structure of the laboratory is a secondary barrier.

4 Risk assessment and risk control of mobile laboratories

4.1 It shall meet the applicable requirements in Chapter 3 of GB 19489-2008.

4.2 The method of laboratory movement and the risks during the movement shall be assessed, and appropriate control measures shall be taken.

4.3 The risks of the environment to the mobile laboratory (not limited to biological risks) shall be assessed, and appropriate control measures shall be taken.

4.4 The environmental risks of mobile laboratories and experimental activities (not limited to biological risks) shall be assessed, and appropriate control measures shall be taken.

4.5 Before and after the maintenance, repair, modification or decommissioning of the laboratory, a risk assessment shall be carried out and appropriate control measures shall be taken.

4.6 The activities undertaken by the laboratory shall be determined, on the basis of risk assessment, in accordance with the classification list of pathogenic microorganisms issued by the relevant national competent authorities.

6.1.3 It shall be safe, reliable, durable, easy to use, meet the requirements of biosafety protection, and meet the requirements of occupational hygiene, environmental protection and energy saving.

6.1.4 If applicable, it shall meet the corresponding requirements of GB 19489-2008.

6.1.5 When test animals are involved, if applicable, the corresponding requirements of GB 14925-2010 shall be met.

6.1.6 If there are no special requirements, it shall meet the design requirements and manufacturing requirements for motorized running devices or transported devices in relevant national regulations or standards.

6.1.7 For a mobile laboratory that is designed and manufactured according to the specific requirements of the customer, if the technical indicators conflict with the requirements of the relevant national regulations or standards, the relevant competent authorities shall be consulted for advice in advance.

6.1.8 Driving positioning system and driving recording system shall be installed.

6.2 Basic requirements

6.2.1 It shall be easy to reach or to be transported to the designated place.

6.2.2 The parts to be transported shall have suitable loading and unloading, handling and fixing devices to meet the requirements of handling and transportation tools. Lifting devices and supporting wheels should be provided to achieve short-distance movement.

6.2.3 The maximum overall dimensions of the laboratory and removable parts should be designed and manufactured with reference to the relevant national standards for removable facilities.

6.2.4 Design and model selection shall be carried out according to the principles and requirements of modularization, integration and standardization, so as to ensure universality and ease of maintenance.

6.2.5 If applicable, maintenance-free equipment shall be selected.

6.2.6 The layout of facilities and equipment, the working space, and the equipment operating mode shall be reasonable, so as to ensure smooth work flow and comply with the principles and requirements of ergonomics.

6.2.7 The implementability of all maintenance works shall be ensured, and the work station space shall be suitable for the needs of human body measurement, posture and use of tools. Mechanical and electrical equipment, if installed, shall not affect the maintenance work.

j) sand and dust;

k) smog (including salt fog);

l) pests (such as fungi, arthropods, rodents).

6.2.16 Documents such as schematic diagrams, operation instructions, maintenance manuals and safety manuals that meet the needs of on-site use, maintenance and repair shall be provided.

6.2.17 The self-propelled laboratory shall be provided with relevant documents of the motorized driving part, which shall meet the requirements of 6.2.16.

6.2.18 When applicable, documents such as good manufacturing practices for mobile laboratories and on-site emergency response plans shall be provided.

7 Requirements for mobile laboratory facilities and equipment

7.1 BSL-1 laboratory

7.1.1 The laboratory may consist of a single laboratory room. The primary barrier mode can be open, but it shall be based on risk assessment, including the content of experimental quality control requirements.

7.1.2 The fixed equipment, table cabinets and wall cabinets of the laboratory shall be firm and connected with the cabin reliably, and the connection shall be smooth and easy to clean.

7.1.3 When the laboratory is moved, there shall be reliable mechanisms and measures to fix items such as instruments and equipment, experimental equipment and seats.

7.1.4 The height of the laboratory shall meet the requirements for equipment installation, and there shall be space for maintenance and cleaning.

7.1.5 The laboratory shall be ventilated. If natural ventilation is used, openable windows and/or ventilation fans may be provided, and the air inlets of openable windows and/or ventilation fans shall be installed with screens that can prevent mosquitoes.

7.1.6 If mechanical ventilation is used, an air-conditioning system with circulating air may be used. The laboratory air-conditioning system shall be reasonably designed according to the area and climatic conditions where the laboratory is used.

7.1.7 A municipal water supply interface should be reserved for the laboratory, and a sewer collection device can be set up. The effluent discharge, if any, shall be based on risk assessment.

7.1.8 In the case of handling irritating or corrosive substances, an eyewash device or an eyewash bottle shall be provided in the laboratory. If a large amount of irritating or corrosive substances are used, an emergency spraying device shall be set up.

7.1.9 UV disinfection lamps and portable disinfection and sterilization devices (such as disinfection sprayers) shall be installed in the laboratory.

7.1.10 When necessary, it shall be equipped with high pressure steam sterilizer or other appropriate disinfection and sterilization equipment.

7.1.11 The average illuminance of the laboratory working area shall not be less than 300 lx.

7.1.12 There shall be a mechanism to maintain smooth communication.

7.2 BSL-2 laboratory

7.2.1 Where applicable, the requirements of 7.1 shall be met.

7.2.2 A buffer room shall be set up at the entrance of the core laboratory room, and the buffer room can also be used as a dressing room for protective clothing.

7.2.3 The doors of the buffer room should be interlocked. If an interlocking door is used, an emergency manual release interlocking switch shall be set near the interlocking door, and, when necessary, the interlocking of the laboratory door shall be released immediately.

7.2.4 During the experiment, the conspicuous position at the entrance of the core laboratory room shall have internationally accepted biohazard warning signs and related information.

7.2.5 The laboratory can adopt natural ventilation or negative pressure ventilation. If a negative pressure ventilation air conditioning system is used, it shall comply with the principle of directional airflow.

7.2.6 The fresh air vents and exhaust vents of the negative pressure ventilation air conditioning system shall be designed to prevent wind, rain, rodents and insects, and the specifications of the air filters shall be determined according to the results of the risk assessment. The fresh air vent shall be 2.5 m higher than the outdoor ground (removable structure can be used); the new air vent shall be set as far away as possible from the exhaust vent.

7.2.7 The core laboratory room shall be equipped with biosafety cabinets or other biosafety isolation devices.

7.2.8 If the exhaust air from biosafety cabinets or other biosafety isolation devices circulates indoors, the laboratory shall be equipped with ventilation conditions.

7.3.8 A non-manual hand washing device or an automatic hand sanitizing device shall be installed near the exit of the core working area of the laboratory.

7.3.9 The core working room of the laboratory should be equipped with a collection and inactivation device for activated toxic wastewater.

7.3.10 The exhaust high-efficiency air filter (or HEPA filter) in the core working room of the level 2 biosafety cabinet laboratory shall have the conditions for in-situ disinfection and leak detection.

7.3.11 The design of the air-conditioning system shall consider the adaptability of the natural environment conditions in the region of use and the heat and humidity load of various equipment; the design of the air supply and exhaust system shall consider the air supply and exhaust of ventilation equipment such as biosafety cabinets and biological isolators.

7.3.12 The air vents, doors, and equipment shall be reasonably arranged to avoid interference and reduce eddy currents and dead ends of airflow in the room.

7.3.13 The supply air of the laboratory shall be filtered through a HEPA filter, and primary- and medium-efficiency filters shall be installed at the same time.

7.3.14 The laboratory shall be provided with a municipal water supply interface and a water storage tank; a backflow prevention device shall be set up between the laboratory water supply and the water storage tank.

7.3.15 The gas supply cylinders or water storage tanks, if any, shall be placed outside the laboratory protection area where they are easy to be replaced and maintained, and installed firmly.

7.3.16 If the experimental operation requires a vacuum device, the vacuum device shall be installed in the core working room, and a high-efficiency filter device shall be installed for the exhaust of the vacuum device.

7.3.17 The conditions for disinfection and sterilization of the laboratory protection area and the ventilation pipes directly connected with it, laboratory equipment and safety isolation devices (including the pipes directly connected with them) shall be provided.

7.3.18 The laboratory shall be equipped with generators for independent power supply, to ensure reliable and sufficient power supply. The power and fuel capacity shall be designed with redundancy, and an external power supply input interface shall be provided.

7.3.19 A special distribution box and ground protection shall be set up in the auxiliary working area; a sufficient number of fixed mains socket-outlet shall be set up in the laboratory; the circuits of important power sockets shall be distributed in separate circuits; leakage detection and alarm devices shall be set up.

7.3.20 The structure and installation of lamps, switches, sockets and other electrical components that need to be installed on the wall and top panels shall meet the airtightness requirements of the area where they are located, and the electrical equipment and wiring shall be securely installed.

7.3.21 Video signal collectors shall be set up in key parts of the laboratory (including outdoor areas), and when necessary, laboratory activities and conditions around the laboratory shall be monitored and recorded in real time. The video signal collector shall have sufficient resolution, and the image storage medium shall have sufficient data storage capacity.

7.3.22 Biosafety cabinets or other biosafety isolation devices, air supply and exhaust fans, lighting, automatic control systems, monitoring and alarm systems, etc. shall be given priority to be equipped with uninterrupted backup power supply, and the power supply shall be maintained for at least 15 minutes. If the conditions are not met, other appropriate protective measures shall be taken according to the risk assessment.

7.3.23 The pressure difference of the core working room pressure (negative pressure) of the level 2 biosafety cabinet laboratory with the outdoor atmospheric pressure shall not be less than 45 Pa, and the pressure difference (negative pressure) with the adjacent area shall not be less than 15 Pa.

7.3.24 The pressure difference of the core working room pressure (negative pressure) of the level 3 biosafety cabinet laboratory with the outdoor atmospheric pressure shall not be less than 30 Pa, and the pressure difference (negative pressure) with the adjacent area shall not be less than 15 Pa.

7.3.25 The minimum ventilation rate in the core working room of the laboratory protection area shall not be less than 12 times/h.

7.4 ABSL-1 laboratory

7.4.1 Where applicable, the requirements of 7.1 shall be met.

7.4.2 The animal feeding room shall be entered through the buffer room or double-door.

7.4.3 Test animal rearing cages shall be set up, and, in addition to safety requirements, the requirements for animal quality and welfare shall also be considered.

7.4.4 The air exhausted from animal rearing cages shall be discharged outdoors through pipes.

7.4.5 Where applicable, the environment and facility conditions of the animal rearing cage shall meet the relevant requirements of GB 14925-2010.

7.5 ABSL-2 laboratory

7.5.1 Where applicable, the requirements of 7.2 and 7.4 shall be met.

and management of the laboratory at the corresponding level, and their personal qualities and abilities shall be competent for on-site work requirements.

8.5 The person in charge of on-site work shall be responsible for formulating and submitting activity plans, risk assessment reports, safety and emergency measures, personnel training and health supervision plans, technical support plans, security assurance and resource requirements, mobile applications, etc. to the laboratory or higher management.

8.6 Site work procedures, safety manuals and security regulations including moving processes shall be developed and maintained.

8.7 When necessary, an isolation belt shall be set up at the mobile laboratory work site.

8.8 The person in charge of on-site work shall be responsible for completing the summary report of each moving task, submitting it to the laboratory or higher management, and archiving it for preservation.

8.9 The signs at the entrance of the laboratory can be set in a non-fixed way, such as listing.

8.10 Safety inspection shall be carried out before moving the laboratory and before starting work (see Appendix C for some safety inspection guidelines), to ensure:

a) The function and status of the facility and equipment are normal;

b) The function and status of the alarm system are normal;

c) The function and status of the emergency equipment are normal;

d) The function and status of the firefighting equipment are normal;

e) Dangerous goods are safely stored;

f) The number and condition of the waste treatment equipment are normal;

g) The required spare parts (see Appendix D) and guarantee conditions meet the requirements;

h) The ability and health status of personnel meet the work requirements;

i) The non-conforming work has been rectified;

j) The required resources meet the job requirements.

8.11 Before carrying out major tasks, internal audits should be carried out on key elements and key links.

Appendix B

(Informative)

Mobile biosafety level 3 laboratory action plan and on-site work plan

B.1 Introduction

The purpose of this Appendix is to help the laboratory formulate the operating procedures in the routine preparation, mobile transfer, and on-site use of the mobile biosafety level 3 laboratory. Laboratories shall keep in mind that the contents of this Appendix may not be fully satisfied or applicable to all types of mobile biosafety level 3 laboratories and on-site environments; specific operating procedures shall be formulated in accordance with the actual situation based on the principles of safety and practicality.

B.2 Preparation

B.2.1 Action plan

B.2.1.1 The laboratory needs to assume in advance various on-site emergency categories (such as epidemic prevention and control after earthquakes, floods, mudslides, typhoons, etc., emergency epidemic handling, large-scale gathering anti-terrorism, terrorist incident handling), according to various relevant experience and historical data in the past, and formulate corresponding action plans for possible situations.

B.2.1.2 The content of the action plan also includes resource requirements and risk assessment, etc., which need to be submitted to the Biosafety Committee and management for approval.

B.2.2 Equipment preparation

B.2.2.1 The required equipment usually includes experimental instruments and equipment (including fixed and movable instruments and equipment in the laboratory), experimental materials and consumables, personal protective equipment, emergency kits, communication equipment, maintenance tools and spare parts, camping equipment and tools, waste disposal equipment, cleaning and disinfection supplies, medicines, firefighting supplies, living equipment and items, personal portable equipment.

B.2.2.2 It is necessary to select suitable and reliable items according to the action plan, on-site environment and climate characteristics, and ensure sufficient quantity.

B.2.2.3 The function and status of key equipment shall be checked and confirmed before departure. Some equipment may require calibration or period verification.

Reagents, disinfectants, etc. need to be checked for the expiration date and the storage conditions shall be considered.

B.2.2.4 Equipment shall be divided into categories according to the nature and packed in special boxes, and the relevant information, including safety and warning information, shall be clearly marked.

B.2.2.5 The equipment that needs to be transported in the laboratory shall be securely fixed.

B.2.2.6 It is necessary to fully consider the living needs and health protection of the staff, so as to ensure the physical and mental state of the staff.

B.2.2.7 It is necessary to assign a special person to be responsible for the whole process of managing the equipment preparation, including the inventory, unpacking, placement, distribution, storage and other work after arriving at the site.

B.2.3 Preparation of mobile laboratories

B.2.3.1 The maintenance of the performance of the mobile laboratory requires daily maintenance, regular opening and operation, and timely repairs when problems are found.

B.2.3.2 Before departure, the performance indicators of the mobile laboratory shall be fully checked and confirmed, and there shall be no problems.

B.2.3.3 It is necessary to practice regularly according to the actual situation that may occur, including movement and experimental performance.

B.2.3.4 Suitable maintenance tools, accessories and auxiliary tools (such as tyre chains, shovels, trailer chains, warning signs), in sufficient quantities, shall be equipped.

B.2.3.5 Evaluate whether an external professional maintenance team is required to provide technical support, and if necessary, sign a relevant agreement.

B.2.4 Personnel preparation

B.2.4.1 The personnel needed on site may include management personnel, experimental personnel, experimental auxiliary personnel, on-site epidemiological investigators, facility maintenance personnel, communication engineers, mechanical engineers, security personnel, life support personnel, medical staff, drivers, etc.

B.2.4.2 All personnel need professional ability and physical fitness to meet the requirements of on-site work.

B.2.4.3 Regardless of the background, situational training and capability confirmation for on-site tasks are required for all personnel.

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