NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Safety requirements for electrical equipment for measurement, control and laboratory use - Part 14: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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Foreword

This document 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".

This document is Part 14 of GB/T 42125 "Safety requirements for electrical equipment for measurement, control and laboratory use". The following parts of GB/T 42125 have been issued.

- Part 10.Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength;

- Part 14.Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes;

- Part 19.Particular requirements for electrically operated valve actuators.

This document replaces GB 4793.9-2013 "Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 9.Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes".

Compared with GB 4793.9-2013, the main technical changes in this document are as follows.

- Add the equipment not included in the scope of this document (see 1.1.2 of this document);

- Change the biohazard symbols in Table 1 (see Table 1; Table 1 of Edition 2013);

- Add the requirements for marking of flow direction [see 5.1.5.101 c) of this Edition];

- Delete equipment transportation, installation and assembly instructions (see 5.4.3 of Edition 2013);

- Change the overview, equipment operation, equipment maintenance, decommissioning or disposal requirements (see 5.4.1, 5.4.4 Note, 5.4.101 of this Edition; 5.4.1, 5.4.4 Note, 5.4.101 of Edition 2013);

- Delete moving parts, accessibility during normal use, and accessibility outside normal use (see 7.2, 7.2.101, and 7.2.102 of Edition 2013);

- Add the exception requirements (see 7.3.2 of this Edition);

- Change the overview (see 8.1 of this Edition; 8.2.1 of Edition 2013);

- Delete toxic and harmful gases and substances (see 13.1 of Edition 2013);

- Add the requirements for biohazardous substances (see 13.101 of this Edition);

- Add overview (see 15.1 of this Edition).

This document identically adopts IEC 61010-2-081.2019 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081.

Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes".

This document has made the following minimal editorial changes.

- To harmonize with the existing documents, change the name of this document to "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 14.Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes".

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

This document was proposed by China Machinery Industry Federation.

This document shall be under the jurisdiction of National Technical Committee on Measurement, Control and Laboratory Electrical Equipment safety of Standardization Administration of China (SAC/TC 338).

The drafting organizations of this document. Beijing Medical Device Inspection and

Research Institute, Medical Device Technology Review Center of the State Food and Drug Administration, Comprehensive Technical and Economic Research Institute of Machinery Industry Instrumentation, Antu Experimental Instruments (Zhengzhou) Co., Ltd., Shenzhen Mindray Biomedical Electronics Co., Ltd., Abbott Trading (Shanghai)

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Versions of standard substituted by this document are.

- It was first issued in 2013 as GB 4793.9-2013;

- This is the first revision.

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 14.

Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

1 Scope and object

Clause 1 of IEC 61010-1 is applicable except as follows.

1.1.1 Equipment included in scope

Replacement.

Replace the text, except the first paragraph, by the following new text.

This document applies to automatic and semi-automatic laboratory equipment for analysis and other purposes.

Automatic and semi-automatic laboratory equipment consists of instruments or systems for measuring or modifying one or more characteristics or parameters of samples, performing the complete process or parts of the process without manual intervention.

Equipment forming part of such a system is within the scope of this document.

Examples of equipment within the scope of this document include.

- analytical equipment;

- automatic sampler (pipettor, aliquoter);

- equipment for sample replication and amplification.

NOTE 1.In the case of analytical equipment, the complete process usually includes the following steps.

- taking a specific quantity of the sample;

- preparing the sample by chemical, thermal, mechanical or other means;

- measurement;

Replace the first paragraph with the following new text.

Markings required by 5.1.2 to 5.2 shall be removable only with a TOOL or by appreciable force and shall remain clear and legible under conditions of NORMAL USE, and resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE, including cleaning and decontaminating agents specified by the manufacturer.

Addition.

Add the following new paragraph after the second paragraph.

If a solvent or reagent specified for use with the equipment could affect the durability of a particular marking, that marking is also rubbed for 30 s with the most frequently used and/or aggressive solvent or reagent to which the equipment is likely to be exposed in NORMAL USE. A representative sample of groups of solvents or reagents likely to have a similar effect can optionally be used.

5.4.1 General Deletion.

Delete Note 2.

5.4.4 Equipment operation Addition.

Add the following note to item h).

NOTE. Manufacturers can find valuable details in the internationally recognized Laboratory Biosafety Manual, published by the World Health Organization. This gives information on decontaminants, their use, dilutions and potential applications. There are also national guidelines that cover these areas.

5.4.101 Removal of equipment from use for repair or disposal Instructions shall be provided to the RESPONSIBLE BODY for eliminating or reducing HAZARDS involved in removal from use, transportation or disposal, or appropriate contact information shall be provided in the instructions.

NOTE. Regional or international requirements can apply.

Conformity is checked by inspection of the documentation.