



Edition 3.0 2019-02 REDLINE VERSION

INTERNATIONAL STANDARD



GROUP SAFETY PUBLICATION

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

IEC 61010-2-081:2019

https://standards.iteh.ai/catalog/standards/iec/7e11f4f0-c308-4aaf-b79c-0a654e7b6146/iec-61010-2-081-2019





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International Standard IEC 61010-2-081 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- adaptation of changes introduced by Amendment 1 of IEC 61010-1:2010;
- added tolerance for stability of AC voltage test equipment to Clause 6.

The text of this International Standard is based on the following documents:

| CDV | Report on voting |
|------------|------------------|
| 66/652/CDV | 66/671A/RVC |

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 61010 series, published under the general title Safety requirements for electrical equipment for measurement, control, and laboratory use, can be found on the IEC website.

This Part 2-081 is to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-081 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.*

Where a particular subclause of Part 1 is not mentioned in this Part 2-081, that subclause applies as far as is reasonable. Where this Part 2-081 states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

- 1) the following print types are used:
 - requirements: in roman type;
 - NOTES: in smaller roman type;
 - conformity and test: in italic type;
 - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.
- 2) subclauses, figures, tables and notes which are additional to those in Part 1 are numbered starting from 101. Additional annexes are lettered starting from AA and additional list items are lettered from aa).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- · reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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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

1 Scope and object

This clause of Part 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 part of IEC 61010 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;
- display, transmission or printing of the results of measurement.

NOTE 2 If all or part of the equipment falls within the scope of one or more other Part 2 documents of IEC 61010 as well as within the scope of this document, considerations have to be is given to those other Part 2 documents.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) IEC 61010-2-101 (in vitro diagnostic (IVD) equipment).

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following new items:

- aa) biohazards:
- bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following new item and note:

aa) handling or manipulation of material outside the equipment.

NOTE Requirements covering these subjects are the responsibility of committees preparing the relevant standards.

2 Normative references

This clause of Part 1 is applicable. Chandards

3 Terms and definitions s://standards.iteh.ai)

This clause of Part 1 is applicable.

4 Tests

IEC 61010-2-081:2019

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

Table 1 - Symbols

Additions:

Add the following new symbol to Table 1:

| Number | Symbol | Publication Reference | Description |
|--------|--|-------------------------|------------------|
| 101 | Background colour - optional Symbol colour - optional | ISO 7000-0659 (2004-01) | Biological risks |
| | Outline / outline colour - optional | | |

Add the following new subclause:

5.1.5.101 Gas and liquid connections

If necessary for safety, the equipment shall be clearly marked near the connector on the equipment with:

- a) a means of identifying the gas or liquid to be used. Where no internationally recognized symbol (including chemical formulae) exists, the equipment shall be marked with symbol 14 of Table 1;
- b) the maximum permitted pressure, or alternatively symbol 14 of Table 1 (see 5.4.3);
- c) flow direction of the gas and liquid, if applicable.

Conformity is checked by inspection.

5.2 Warning markings

Replacement:

Replace the first paragraph by the following:

Warning markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.101, 6.1.2 b), 7.3.2 b) 3), 7.4, 10.1, 13.2.2 and 13.101 shall meet the following requirements.

5.3 Durability of markings

Replacement:

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 in the second paragraph.

5.4.4 Equipment operation

Replacement:

Replace the text in item h) by the following item h) and note:

h) a statement listing any potentially poisonous or injurious gases or substances that can be liberated from the equipment, and possible quantities;

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.

Addition:

Add the following new subclause:

5.4.101 Removal of equipment from use for repair or disposal

Instructions shall be provided for 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.

Protection against electric shock

This clause of Part 1 is applicable except as follows:

6.8.3.1 The AC voltage test

Replacement:

Replace the first sentence by the following new sentence:

The voltage tester shall be capable of maintaining the test voltage throughout the test within ±5 % of the specified value.

Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows:

7.3.2 Exceptions

Replacement:

Replace the text in item b) 3) by the following new text:

there are warning markings prohibiting access by untrained OPERATORS. Markings shall be placed within the area requiring maintenance where they can alert the OPERATOR to the HAZARD. As an alternative, symbol 14 of Table 1 can be used, with the warnings included in the documentation.

Addition:

Add the following new item: