IEC 61010-2-081

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

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

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-081: Prescriptions particulières pour les appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et autres usages

IEC 61010-2-081:2001+A1:2003

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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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 consolidated version of IEC 61010-2-081 consists of the first edition (2001) [documents 66/260/FDIS and 66/269/RVD] and its amendment 1 (2003) [documents 66/327/FDIS and 66/332/RVD].

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience.

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

This part 2 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the second edition (2001). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

This part 2 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety 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, that subclause applies as far as is reasonable. Where this part 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 or figures which are additional to those in part 1 are numbered starting from 101; additional annexes are lettered starting from AA.

Annexes AA and BB form an integral part of this standard.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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 Scope

Replacement:

This part 2 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 standard.

Examples of equipment within the scope of this standard 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 standards of IEC 61010 as well as within the scope of this standard, it will also need to meet the requirements of those other parts 2 standards.

1.2 Object

1.2.1 Aspects included in scope

Replacement:

Replace the first sentence by the following:

The purpose of this standard is to ensure that the design and methods of construction used provide a high degree of protection at a TOLERABLE RISK for the OPERATOR and the surrounding area, using RISK management where specified (see 7.2.101 and annex AA).

Addition:

Add two new items:

a) biohazards;

b) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add a new item and the following note:

g) 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 except as follows:

Addition:

IEC 60068-2-75:1997, *Environmental testing – Part 2-75: Test – Test Eh: Hammer tests*

3 Terms and definitions

This clause of part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Additions:

Additional definitions:

3.101
HARM
physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

3.102
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

[ISO/IEC Guide 51:1999, definition 3.2]

3.103
TOLERABLE RISK
RISK which is accepted in a given context based on the current values of society

[ISO/IEC Guide 51:1999, definition 3.7]

NOTE TOLERABLE RISK is the result of a balance between the ideal of absolute safety, the demands to be met by a product, process or service, and factors such as benefit to the user, suitability of purpose, cost effectiveness, RISK evaluation, conventions of the society concerned, and the state of the art.

4 Tests

This clause of part 1 is applicable except as follows:

4.4.2 Application of fault conditions

Addition:

Additional subclause:

4.4.2.101 Incorrect voltage selection

Multivoltage equipment that can be set by the OPERATOR to different supply voltages shall be set to each voltage in turn and then connected to all other RATED supply voltages in turn.

5 Marking and documentation

This clause of part 1 is applicable except as follows:

5.1.1 General

Replacement:

Replace the third paragraph by the following:

Letter symbols for quantities and units shall be in accordance with IEC 60027. Internationally recognized symbols, including those of Table 1, shall be used as far as possible. If other additional symbols are required, it shall not be possible to confuse them with the international symbols. There are no colour requirements for symbols except for symbol 101 (see Table 1). Graphic symbols shall be explained in the documentation.

Table 1 – Symbols

Addition:

Add the following new symbol:

Number	Symbol	Publication	Description
101	 Background colour – yellow Symbol and outline – black	ISO 7000 – 0659	Biohazard

5.1.5 TERMINALS, connections and operating devices

Additions:

Add the following new note 3:

NOTE 3 All connectors, controls and indicators necessary for use by the OPERATOR should be marked.

Additional subclause:

5.1.5.101 Gas and liquid connections

The equipment shall be clearly marked near to 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).

Conformity is checked by inspection.

5.2 Warning markings

Replacement:

Replace the fifth paragraph by the following five paragraphs:

Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1.

Equipment that can be hazardous due to the use of chemical substances shall be marked with the appropriate symbol, or (if none is available) symbol 14 of Table 1.

Protective covers shall be marked to warn the OPERATOR not to open or remove them except as permitted by 7.2.101 or 7.2.102.

Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during NORMAL USE shall be marked with symbol 101 of Table 1.

Other warning markings are specified in 5.1.5.1 c), 6.1.2 b), 6.5.1.2 g), 6.6.2, 7.2 c), 7.2.101 f), 7.2.102 c), 7.3, 10.1, 13.2.2.

5.3 Durability of markings

Replacement:

Replace the first paragraph by the following new paragraph:

Markings required by 5.1.2 to 5.2 shall be permanently affixed 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 after the first paragraph a new paragraph to the conformity as follows:

If a solvent or reagent specified for use with the equipment could affect the durability of particular marking, that marking is also rubbed for 30 s with each solvent or reagent (or with a representative sample of groups of solvents or reagents likely to have a similar effect).

5.4.1 General

Deletion:

Delete the note to the second paragraph.

Addition:

Add a new third paragraph as follows:

Information shall be given about any RISKS not reduced to a TOLERABLE RISK level by the protective measures specified in this standard. If there is a need for training or for the use of additional protective devices or personal protective equipment to reduce RISKS to a TOLERABLE RISK level, these shall be specified.

5.4.3 Equipment installation

Replacement:

Replace the title and text by the following:

5.4.3 Equipment transportation, installation and assembly instructions

Documentation for the RESPONSIBLE BODY shall include the following as applicable:

a) instructions for transportation after delivery to the RESPONSIBLE BODY;
b) floor loading requirements;
c) individual weights of principal heavy sub-assemblies;
d) location and mounting instructions, including the space required for ventilation, and for safe and efficient OPERATOR maintenance;
e) assembly instructions;
f) instructions for protective earthing;
g) the sound data required by 12.5.1;
h) instructions relating to the handling, containment and exhaust of hazardous substances, including any requirements for preventing back-syphonage;
i) any drainage systems required where a HAZARD could occur from the discharge of biological and chemical substances and hot fluids;
j) details of protective measures relating to hazardous radiation (see clause 12);
k) instructions for connections to the supply;
l) for PERMANENTLY CONNECTED EQUIPMENT only:
    1) mains supply requirements and details of connections, including the RATED temperature of the cable required at maximum RATED ambient temperature;
    2) requirements for any external switches, circuit-breakers (see 6.11.2.1) or overcurrent protection devices (see 9.5). A recommendation that a switch or circuit breaker be near the equipment shall also be included if this is necessary for safety;
m) requirements for special services (for example air, cooling liquid) including pressure limits.

Conformity is checked by inspection of the documentation.