IEC 61010-2-081

Edition 2.0 2015-01
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

withdrawn

IEC 61010-2-081:2015-01 RLV(en)

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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

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 second edition cancels and replaces the first edition published in 2001 and its Amendment 1 (2003). It constitutes a technical revision and includes the following significant changes from the first edition, as well as numerous other changes:

- excluded IEC 61010-2-101 (IVD Equipment) from scope. This separates IEC 61010-2-081 and IEC 61010-2-101 equipment;
- added biological risks symbol to Table 1 in Clause 5;
- added requirement for statement on hazardous substances and gases in Instructions for Use to Clause 5;
- Added marking requirement for flow direction to Clause 5;
- added requirement for OPERATOR maintenance instructions to Clause 7;
- excluded equipment whose size and weight make unintentional movement unlikely from drop test in Clause 8;
- added requirement for biohazard marking to Clause 13;
- added requirement for interlock systems containing electric/electronic or programmable components to Clause 15.

The text of this standard is based on the following documents:

FDIS	Report on voting
66/544/FDIS	66/559/RVD

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

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

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

This Part 2-081 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-081 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;*

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- 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.

The committee has decided that the contents of this publication will remain unchanged until the stability 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.

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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

Withdrawn

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 by the following:

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 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~~ considerations have to be given to those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following item:

aa) IEC 61010-2-101 (IVD Equipment)

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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 the following items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following item and note:

~~g~~ 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 ~~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~~

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~~[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

Additions:

Add the following symbol to Table 1:

Number	Symbol	Publication	Description
101	Background colour – ~~yellow~~ optional; Symbol colour – optional; Outline / outline colour – ~~black~~ optional;	ISO 7000-0659 (2004-01)	~~Biohazard~~ Biological risks

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~~**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.~~

Add the following subclause:

5.1.5.101 Gas and liquid connections

If necessary for safety, 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);

c) flow direction of the gas and liquid, if applicable.

Conformity is checked by inspection.

5.2 Warning markings

Replacement:

Replace the ~~fifth~~ first 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.~~

Warning markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.101, 6.1.2 b), ~~6.5.1.2 g), 6.6.2, 7.2 c), 7.2.101 f), 7.2.102 c),~~ 7.3.2 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 by the following paragraph:

Markings required by 5.1.2 to 5.2 shall be ~~permanently affixed~~ 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:

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Add after the ~~first~~ second paragraph the following paragraph:

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~~ the most frequently used and/or aggressive solvent or reagent to which the equipment is likely to be exposed in NORMAL USE. ~~(or with~~ 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.

~~*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;~~

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~~m) requirements for special services (for example air, cooling liquid) including pressure limits.~~

~~*Conformity is checked by inspection of the documentation.*~~

5.4.4 Equipment operation

Replacement:

~~Instructions for use shall include if applicable:~~

~~a) details of operating controls and their use in all operating modes with any sequence of operation;~~

~~NOTE 1 IEC 60073 gives guidance on colours and symbols of operating controls.~~

~~b) an instruction not to position the equipment so that it is difficult to operate the disconnecting device (see 6.11);~~

~~c) instructions for interconnections to accessories and other equipment, including details of suitable accessories, detachable parts and any special materials;~~

~~d) limits for intermittent operation;~~

~~e) an explanation of symbols used on the equipment and, where HAZARDS are involved, the reason for using a symbol in each particular case;~~

~~f) instructions for any actions to be taken by an OPERATOR in case of a malfunction;~~

~~g) instructions and recommendations for cleaning and decontamination, with materials recommended (see 11.2);~~

~~h) instructions for the disposal of waste;~~

~~i) if NORMAL USE involves the handling of hazardous substances, instructions on correct use and any need for training or personal protection measures;~~

~~j) if there could be contact with the skin when handling potentially infectious substances (such as human samples or reagents), the need to use protective gloves;~~

~~k) if the equipment could emit hazardous aerosol vapours in NORMAL USE, instructions for protection of the mouth, nose or eyes;~~

~~l) if potentially hazardous visible or invisible radiation could be emitted, instructions and requirements for protective devices, such as protective glasses;~~

~~m) instructions relating to access to moving parts (see 7.2.101 and 7.2.102).~~

~~There shall be a statement in the instructions that, if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.~~

~~NOTE 2 Manufacturers should be aware of 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.~~

~~NOTE 3 Cleaning and decontamination may be necessary as a safeguard when equipment and its accessories are maintained, repaired, or transferred. Manufacturers should provide a format for RESPONSIBLE BODIES to certify to those maintaining, repairing or transferring equipment that such a treatment has been carried out.~~

~~*Conformity is checked by inspection of the documentation.*~~

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;

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:

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Add the following subclauses:

5.4.101 Removal of equipment from use for repair or disposal

Instructions shall be provided for the RESPONSIBLE BODY for eliminating or reducing HAZARDS involved in removal from use, transportation or disposal~~. These instructions shall include requirements for minimizing biohazards, if any~~, 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.

6 Protection against electric shock

This clause of Part 1 is applicable.

7 Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows:

~~**7.2 Moving parts**~~

~~*Deletion*~~

~~*Delete paragraphs two and three.*~~

~~*Addition:*~~

~~*Additional subclauses:*~~

~~**7.2.101 Accessibility during NORMAL USE**~~

~~As an exception, if moving parts are unavoidably exposed in NORMAL USE, RISK management (see annex AA) shall be carried out to establish whether the moving parts could cause injury to the OPERATOR. Any RISKS shall be minimized as far as practible by protective measures, in the following order of priority:~~

~~a) protective devices (Interlock systems or other means, removable only with a TOOL);~~

~~b) protective covers;~~

~~c) mechanical BARRIERS;~~

~~d) sufficient distance between safe areas and moving parts;~~

~~e) warning signals (audible or visible);~~

~~f) warning markings (see 5.2).~~

~~Measures b) to d) shall be combined with warnings regarding hazardous areas (see 5.4.1).~~

~~If moving parts are unavoidably exposed during NORMAL USE, the instructions shall specify that procedures which could result in injury are carried out only by OPERATORS who have been warned of the potential HAZARDS and have received adequate training in carrying out the procedures in the safest possible manner.~~

~~*Conformity is checked by inspection and as specified in annex AA.*~~

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