IEC 61010-2-081

Edition 3.0 2019-02
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

IEC 61010-2-081:2019-02 RLV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

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2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
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5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

3 Terms and definitions

This clause of Part 1 is applicable.

4 Tests

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 Outline / outline colour – optional	ISO 7000-0659 (2004-01)	Biological risks

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.

6 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.

7 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:

b) 4) there are OPERATOR maintenance instructions that specify safe maintenance procedures.

8 Resistance to mechanical stresses

This clause of Part 1 is applicable except as follows:

8.1 General

Replacement:

Replace the text of item 3) by the following new text:

3) except for FIXED EQUIPMENT, for equipment with a mass over 100 kg, or for equipment whose size and weight make unintentional movement unlikely and which is not moved in NORMAL USE, the appropriate test of 8.3. The equipment is not operated during the tests.

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids and solid foreign objects

This clause of Part 1 is applicable.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new subclause:

13.101 Biohazardous substances

Equipment that can be potentially biohazardous due to the use of biohazardous substances shall be prominently marked with symbol 101 of Table 1, or the appropriate international symbol, or (if none is available) symbol 14 of Table 1.

At minimum, a biohazard symbol shall be located near the sampling area and be visible in NORMAL USE.

Biohazard symbols shall be located near biohazardous areas accessed during OPERATOR maintenance and visible only during this maintenance.

Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during NORMAL USE or a biohazardous drain connection shall be marked with an appropriate biohazard symbol.

14 Components and subassemblies

This clause of Part 1 is applicable.

15 Protection by interlocks

This clause of Part 1 is applicable except as follows.

15.1 General

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL) (all parts) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 RISK assessment

This clause of Part 1 is applicable.

Annexes

The annexes of Part 1 are applicable.

Bibliography

Addition:

Add the following new references:

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

IEC 62061, *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

World Health Organization, *Laboratory biosafety manual*

IEC 61010-2-081

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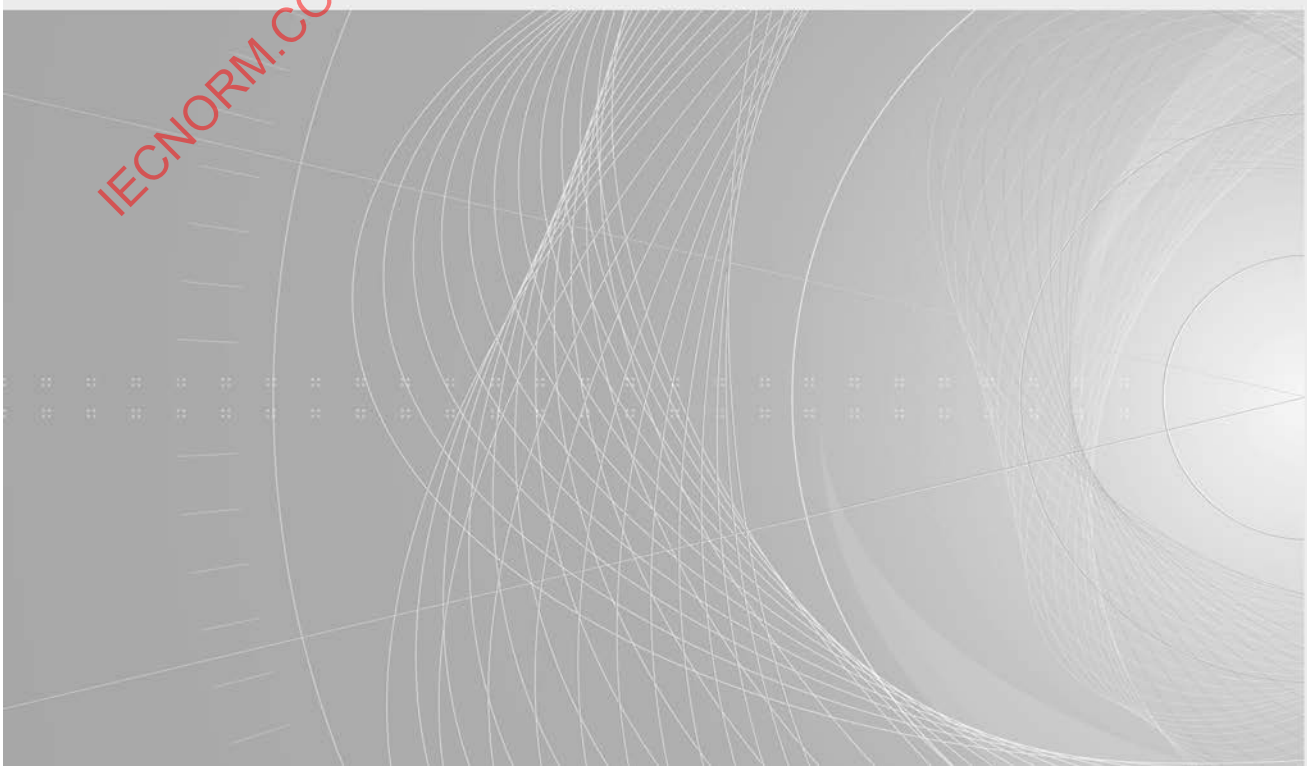
GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

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

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



IEC 61010-2-081:2019-02(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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).

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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, consideration 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.

3 Terms and definitions

This clause of Part 1 is applicable.

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

Table 1 – Symbols

Addition:

Add the following new symbol to Table 1:

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

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.

5.3 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.

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.

Addition:

Add the following new subclause:

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.

6 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.

7 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:

b) 4) there are OPERATOR maintenance instructions that specify safe maintenance procedures.

8 Resistance to mechanical stresses

This clause of Part 1 is applicable except as follows:

8.1 General

Replacement:

Replace the text of item 3) by the following new text:

3) except for FIXED EQUIPMENT, for equipment with a mass over 100 kg, or for equipment whose size and weight make unintentional movement unlikely and which is not moved in NORMAL USE, the appropriate test of 8.3. The equipment is not operated during the tests.

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids and solid foreign objects

This clause of Part 1 is applicable.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new subclause:

13.101 Biohazardous substances

Equipment that can be potentially biohazardous due to the use of biohazardous substances shall be prominently marked with symbol 101 of Table 1, or the appropriate international symbol, or (if none is available) symbol 14 of Table 1.

At minimum, a biohazard symbol shall be located near the sampling area and be visible in NORMAL USE.

Biohazard symbols shall be located near biohazardous areas accessed during OPERATOR maintenance and visible only during this maintenance.

Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during NORMAL USE or a biohazardous drain connection shall be marked with an appropriate biohazard symbol.

14 Components and subassemblies

This clause of Part 1 is applicable.

15 Protection by interlocks

This clause of Part 1 is applicable except as follows.

15.1 General

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL) (all parts) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 RISK assessment

This clause of Part 1 is applicable.

Annexes

The annexes of Part 1 are applicable.

Bibliography

Addition:

Add the following new references:

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

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ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

World Health Organization, *Laboratory biosafety manual*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-081: Exigences particulières pour les appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et à d'autres usages

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La Norme internationale IEC 61010-2-081 a été établie par le comité d'études 66 de l'IEC: Sécurité des appareils de mesure, de commande et de laboratoire.

Elle a le statut d'une publication groupée de sécurité conformément au Guide IEC 104.

Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

- adaptation des modifications introduites par l'Amendement 1 de l'IEC 61010-1:2010;
- ajout de la tolérance de stabilité pour les appareils d'essai de tension en courant alternatif à l'Article 6.

Le texte de cette Norme internationale est issu des documents suivants:

CDV	Rapport de vote
66/652/CDV	66/671A/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Une liste de toutes les parties de la série IEC 61010, publiées sous le titre général *Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*, peut être consultée sur le site web de l'IEC.

La présente Partie 2-081 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010) et de son Amendement 1 (2016), ci-après dénommée la Partie 1.

La présente Partie 2-081 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à la transformer en norme IEC: *Exigences particulières pour les appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et à d'autres usages.*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2, ce paragraphe s'applique pour autant qu'il est raisonnable. Lorsque cette partie spécifie "addition", "modification", "remplacement", ou "suppression", il convient d'adapter l'exigence, la modalité d'essai ou la note correspondante de la Partie 1 en conséquence.

Dans la présente norme:

1) les caractères d'imprimerie suivants sont employés:
   - exigences: caractères romains;
   - NOTES: petits caractères romains;
   - *conformité et essai: caractères italiques;*
   - termes définis à l'Article 3 et utilisés dans cette norme: PETITES CAPITALES EN CARACTERES ROMAINS.
2) les paragraphes, figures, tableaux et notes qui viennent en supplément de ceux de la Partie 1 sont numérotés à partir de 101. Les annexes supplémentaires sont désignées par des lettres à partir de AA et les listes supplémentaires à partir de aa).

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. A cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-081: Exigences particulières pour les appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et à d'autres usages

1 Domaine d'application et objet

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

Remplacer le texte, excepté le premier alinéa, par le nouveau texte suivant:

La présente partie de l'IEC 61010 s'applique aux appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et à d'autres usages.

Les appareils de laboratoire automatiques et semi-automatiques comprennent les instruments ou systèmes utilisés pour mesurer ou modifier un ou plusieurs paramètres ou caractéristiques d'échantillons, réalisant tout ou partie du processus sans intervention manuelle. Les appareils faisant partie d'un tel système sont couverts par le domaine d'application du présent document.

Exemples d'appareils entrant dans le domaine d'application du présent document:

- appareils réalisant des analyses;
- échantillonneurs automatiques (pipeteur, aliquoteur);
- appareils réalisant la réplication ou l'amplification d'échantillon.

NOTE 1 En ce qui concerne les appareils réalisant des analyses, le processus complet comprend habituellement les phases suivantes:

- prélèvement d'une quantité déterminée de l'échantillon;
- préparation de l'échantillon par des moyens chimiques, thermiques, mécaniques ou autres;
- mesurage;
- affichage, transmission ou impression des résultats de mesure.

NOTE 2 Si l'appareil dans sa totalité ou certains de ses sous-ensembles relèvent du domaine d'application d'une ou de plusieurs autres Parties 2 de l'IEC 61010 ainsi que du domaine d'application du présent document, ces autres Parties 2 sont également prises en considération.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant:

aa) IEC 61010-2-101 (appareils de diagnostic in vitro, DIV).

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter les nouveaux points suivants:

aa) dangers biologiques;

bb) substances chimiques dangereuses.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le nouveau point et la nouvelle note ci-dessous:

aa) la manutention ou la manipulation de substances en dehors de l'appareil.

NOTE Les exigences applicables à ces sujets sont de la responsabilité des comités établissant les normes appropriées.

2 Références normatives

L'article de la Partie 1 est applicable.

3 Termes et définitions

L'article de la Partie 1 est applicable.

4 Essais

L'article de la Partie 1 est applicable.

5 Marquage et documentation

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

Tableau 1 – Symboles

Addition:

Ajouter le nouveau symbole suivant dans le Tableau 1:

Numéro	Symbole	Référence	Description
101	 Couleur du fond – facultatif Couleur du symbole – facultatif Contour / couleur du contour – facultatif	ISO 7000-0659 (2004-01)	Risques biologiques