SVENSK STANDARD SS-EN IEC 61010-2-081



Fastställd 2020-09-23 Utgåva 3 Sida 1 (1+15) Ansvarig kommitté SEK TK 66

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Elektrisk utrustning för mätning, styrning och för laboratorieändamål – Säkerhet –

Del 2-081: Särskilda fordringar på hel- och halvautomatiska laboratorieutrustningar för analys och liknande ändamål

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

Som svensk standard gäller europastandarden EN IEC 61010-2-81:2020. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61010-2-81:2020.

Nationellt förord

Europastandarden EN IEC 61010-2-81:2020

består av:

- europastandardens ikraftsättningsdokument, utarbetat inom CENELEC
- IEC 61010-2-081, Third edition, 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

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 61010-1, utgåva 3, 2010 och dess separat utgivna tillägg.

Tidigare fastställd svensk standard SS-EN 61010-2-081, utgåva 2, 2015, gäller ej fr o m 2023-05-22.

ICS 19.080.00; 71.040.10

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN IEC 61010-2-081

May 2020

ICS 19.080; 71.040.10

Supersedes EN 61010-2-081:2015 and all of its amendments and corrigenda (if any)

English Version

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)

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)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-081: Besondere Anforderungen für automatische und semiautomatische Laborgeräte für Analysen und andere Zwecke (IEC 61010-2-081:2019)

This European Standard was approved by CENELEC on 2019-03-19. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Ref. No. EN IEC 61010-2-081:2020 E

European foreword

This document (EN IEC 61010-2-081:2020) consists of the text of IEC 61010-2-081:2019 prepared by IEC/TC 66 "Safety of measuring, control and laboratory equipment".

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2020-11-22 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-05-22

This document supersedes EN 61010-2-081:2015 and all of its amendments and corrigenda (if any).

EN IEC 61010-2-081:2020 includes the following significant technical changes with respect to EN 61010-2-081:2015:

- a) adaptation of changes introduced by Amendment 1 of IEC 61010-1;
- b) added tolerance for stability of a.c. voltage test equipment to Clause 6.

NOTE This document is based on EN 61010-1:2010 and its amendment, EN 61010-1:2010/A1:2019.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 61010-2-081:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61010-2-101 NOTE Harmonized as EN 61010-2-101

IEC 62061 NOTE Harmonized as EN 62061

ISO 13849 (series) NOTE Harmonized as EN ISO 13849 (series)

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 61010-1:2010/A1:2019 is applicable with the following additions:

Pu	<u>blication</u>	<u>Year</u>	<u>Title</u>	EN/HD and IEC/ISO	<u>Year</u>
+ (• •	2005 2010 2010 2012 2015	Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems	EN 62061	2005 2010 2010 2013 2015
IS	O 13849-1	2015	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design	EN ISO 13849-1	2015
IS	O 13849-2	2012	Safety of machinery - Safety-related parts of control systems - Part 2: Validation	EN ISO 13849-2	2012

CONTENTS

FOI	REWORD	3
1	Scope and object	5
2	Normative references	6
3	Terms and definitions	6
4	Tests	6
5	Marking and documentation	6
6	Protection against electric shock	8
7	Protection against mechanical HAZARDS	8
8	Resistance to mechanical stresses	8
9	Protection against the spread of fire	9
10	Equipment temperature limits and resistance to heat	9
11	Protection against HAZARDS from fluids and solid foreign objects	9
12	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	9
13	Protection against liberated gases and substances, explosion and implosion	9
14	Components and subassemblies	9
15	Protection by interlocks	9
16	HAZARDS resulting from application	10
17	RISK assessment	10
Ann	nexes	10
Bibl	liography	11
Tab	ole 1 – Symbols	6

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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 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.

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.