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IEC 61010 SERIES:
MASTER THE CHALLENGE & KEEP UP WITH THE CHANGES

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CONTENTS

INTRODUCTION

The IEC 61010 series of standards has a long history with the First Edition of IEC 61010-1 published in 1990, followed by various particular (Part 2) standards shortly after. Over the years, the standard underwent significant technical changes. Amendment 1 to Edition 3 was issued in 2016; the work on future Edition 4 has already begun.

IEC 61010-1:2010, Edition 3 is a widely accepted safety standard for laboratory, process control, and test & measurement equipment. With its broad scope it covers professional and non-professional products in various industries ranging from medical to industrial – examples include in-vitro diagnostic devices, machinery, electrically-operated valves, heating and cooling equipment, and programmable logic controllers. The product specific hazards are addressed by particular standards (IEC 61010-2-x) which are to be used in conjunction with the general standard IEC 61010-1. An exception is IEC 61010-031 for probe assemblies which is a part of the IEC 61010 family but is a standalone standard.

The technical committees developing the standard consist of members from many different countries and represent manufacturers, test laboratories, industry organizations, and others. Their expertise is the basis to ensure the standard addresses all safety related issues by providing technical specifications or other precise criteria as technical guidance or definition. Changing or new technologies, and field experience with products in the scope of IEC 61010-1, are drivers for revising the existing standard or developing new Part 2 standards. These changes and new requirements should be well understood by the different teams within your company including compliance, design, engineering, regulatory, and marketing.

To offer guidance on the changes to the standard in the last few years, this whitepaper will give you an overview on the latest developments in regard to the IEC 61010 family, the new and revised requirements, and the status of Edition 3 and Amendment 1 in major markets. We will also look beyond IEC 61010 by giving an overview on additional standards / requirements which may apply for your product which may either be referenced by IEC 61010 or are required by regulatory bodies.

WHAT IS THE "IEC"?

The International Electrotechnical Commission (IEC) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic, and related technologies.

Close to 20,000 experts from industry, commerce, government, test and research labs, academia, and consumer groups participate in IEC Standardization work.

OVERVIEW: GENERAL REQUIREMENTS: IEC 61010-1

Content of IEC 61010-1:2010 Edition 3

The standard specifies the safety requirements which are generally applicable to all equipment in the scope – electrical equipment for measurement, control, and laboratory use. For specific types of equipment the requirements are supplemented or modified by particular standards. Note that more than one particular standard may apply which must always be used in conjunction with the base standard.

The purpose of the standard is to ensure that hazards to the operator and the surrounding area are reduced to a tolerable level. Reliable function, performance, or other properties of equipment not related to safety as well as the effectiveness of transport packaging are not covered by IEC 61010-1. It excludes EMC requirements (IEC 61326 series) and protective measures for explosive atmospheres (IEC 60079 series).

The requirements are based on the particular types of hazards that may apply for the product under testing including:

- Electric shock and burn (Clause 6)
- Mechanical hazards (Clause 7)
- Effects of mechanical stresses (Clause 8)
- Spread of fire from the equipment (Clause 9)
- Excessive temperatures (Clause 10)
- Effects of fluids and fluid pressure (Clause 11)
- Effects of radiation, including laser sources, and sonic and ultrasonic pressure (Clause 12)
- Liberated gases, explosion and implosion (Clause 13)

Clause 14 covers requirements for safety critical components and subassemblies, with clause 15 going into further detail on protection by interlocks.

Hazards resulting from the application such as reasonably foreseeable misuse and ergonomic factors are addressed in Clause 16. To deal with hazards or environments not fully addressed in Clauses 6 to 16, the standard specifies requirements for risk assessment in Clause 17.

Compliance with the requirements of IEC 61010-1 is verified by the following methods: inspection, type tests, routine tests, and risk assessment.

In each of the above clauses, specific design and construction requirements are given. The conformity is checked by carrying out all applicable tests under reference test conditions and under fault conditions. These tests can range from a visual inspection to a very complex test program such as qualification of conformal coatings used on printed wiring boards to reduce the pollution degree (Annex H). Tests needed to support a risk assessment are carried out in the combinations of conditions and operations determined during the risk assessment.

Marking (including identification, mains supply, fuses, terminals, switch/breakers and warning markings and others) and documentation necessary for safety purposes play an important role in IEC 61010-1, with detailed requirements included in clause 5.

Various Annexes are included in the standard, some of which are informative only. The following are normative and thus are required for compliance with this standard where applicable:

- Annex A: Measuring circuits for touch current
- Annex B: Standard test fingers
- Annex C: Measurement of clearances and creepage
- Annex D: Parts between which insulation requirements are specified
- Annex F: Routine tests
- Annex H: Qualification of conformal coatings
- Annex K: Insulation requirements not covered by 6.7

Risk Assessment

Clause 17 deals with hazards and environments not covered by the standard, supplemented by an informative Annex J dealing with risk assessment. IEC 61010-1 Edition 3 defines risk assessment as a three-step process:

Step 1 — Risk analysis
Step 2 — Risk evaluation
Step 3 — Risk reduction

The risk analysis determines the hazards that could lead to a risk based upon known variables. Upon completing the risk analysis, manufacturers must perform a risk evaluation to determine if any of the risks determined are unacceptable. This evaluation is based on the manufacturer's risk acceptability criteria, which weigh the severity of the risk against the probability the risk will occur.

After determining which risks are unacceptable, the manufacturer must perform risk reduction to reduce the risk to an acceptable level. Risk reduction is a prioritized function in which the following are considered as the means for risk reduction:

3-STEP PROCESS FOR RISK ASSESSMENT

1. **Risk Analysis**
2. **Risk Evaluation**
3. **Risk Reduction**

First — Eliminating the risk through design, if possible
Then — Implementing protective measures, to remove the risk, and
Finally — Providing information to the end user via markings or instructions for use

Risk assessment is also mentioned in other clauses. Examples include

- Clause 7.3, which allows risk assessment for mechanical hazards to body parts if the conditions specified in 7.3.4 (Limitation of force and pressure) and 7.3.5 (Gap limitations between moving parts) are not being met
- Clause 16.1, Cases of reasonably foreseeable misuse that are not addressed by specific requirements in the standard, which shall be addressed by risk management
- Clause 16.2, Ergonomic aspects where conformity shall be checked by evaluation of the risk assessment documentation (e.g. limitation of body dimensions, accessibility of controls and arrangements of terminals)

Changes in IEC 61010-1:2010 Amendment 1:2016

Amendment 1 revises various clauses in the standard, most of which can be considered minor such as additions to standard references, and clarifications. Changes which may have an impact on the product's design, construction, tests, markings and documentation include the following:

Clause	Covers	Changes (Summarized)
5.2	Warning markings	If, as per the instructions for use, the operator is permitted to gain access to a location which in normal use may present a hazard, a warning marking consisting of symbol 14 (Caution) shall be provided, along with other symbols to indicate the nature of the hazard where appropriate, with a warning text included in the instructions for use.
5.4.3	Equipment installation and commissioning instructions	Requirements were expanded in regard to warnings against hazards which could occur during commissioning or resulting from improper installation.
6.3	Limit values for accessible parts	The voltage limits for accessible parts have been reduced to the levels for Normal Condition (30 V_{rms}, 42.4 V_{pk}, 60 V_{dc}) and Single Fault Condition (50 V_{rms}, 70 V_{pk}, 120 V_{dc}). This is now in line with the lower limits stated in ANSI/UL 61010-1 which adopts the IEC text with national deviations.
6.11.4	Disconnecting devices	A circuit-breaker used for disconnection shall meet IEC 60947-2; an equipment switch used for the same purpose shall meet IEC 60947-3.
7.3.4	Moving parts – Limitation of force and pressure	The definition of contact pressure was clarified by giving details on the width of body parts and a description how to determine the contact area; a calculation example has been added.
11.6	Equipment rated with a degree of ingress protection (IP code)	Equipment with IP rating: This clause has been completely rewritten to better clarify the test conditions and conformity requirements
11.7.2	Fluid pressure and leakage – Leakage and rupture at high pressure	The hydraulic test has been rewritten and Figure 16 added to clarify the ratio between test pressure and maximum working pressure.
12.3	Protection against optical radiation	The requirements for optical radiation for equipment with lamps and lamp systems were expanded to include UV, visible, and infrared radiation, requiring an evaluation to IEC 62471 except for sources considered photobiologically safe. Labelling for lamps and lamp systems classified as Risk Groups 1, 2 or 3 is required to be in line with IEC TR 62471-2.
13.1	Protection against poisonous and injurious gases and substances	It was clarified that that equipment shall not liberate dangerous amounts of hazardous substances in both normal and single fault condition, and that the operator shall not be directly exposed to a harmful quantity of the substance if potentially-hazardous substances are liberated,
14.8	Circuits used to limit transient overvoltages	The compliance criteria were adjusted and now require the limiting circuit to safely suppress the impulse and continue to function properly after the test.

PARTICULAR STANDARDS: PRODUCT SPECIFIC REQUIREMENTS

Particular standards (IEC 61010-2-x) are intended to be used in conjunction with IEC 61010-1. They supplement or modify the corresponding clauses in IEC 61010-1 so as to "convert" that publication to a product-specific safety standard.

An example would be for equipment in the scope of IEC 61010-2-010 (Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials), which, if used in conjunction with the general standard, becomes the following standard: "Safety requirements for laboratory equipment for the heating of materials".

Manufacturers should pay specific attention to the information in the introduction of each Part 2 standard to ensure it is being applied correctly and is applicable to the product in question. This is important because some Part 2 standards which may seem to be applicable for the specific product can exclude one another. Because determining the correct standards can be a complex task, some standards include specific guidance in regard to the applicability of Part 2s.

It is important to ensure that the edition of IEC 61010-1 used with the particular (-2) standard is the one referenced in the particular standard being applied for the product. Note that IEC 61010-1 may be used without a Part 2 if no particular standard has been published for the specific product type. Also note that IEC 61010-031 is a standalone standard but has been added to the table for a complete overview on the standards within the IEC 61010 series.

The following table gives an overview on standards in the IEC 61010 series that have been published or will be published in the near future:

GETTING IT RIGHT THE FIRST TIME

Be sure to read/review the Part 2 information carefully to ensure that you are applying the correct standard for your product. If you are unsure, contact Intertek or whichever laboratory you intend to partner with for testing.

Product Category	Standard	Scope	Notes	
Measurement, control and laboratory equipment	IEC 61010-1	(General) electrical equipment for measurement, control and laboratory use	Used in conjunction with applicable particular (Part 2) standard(s) for the specific product type. Application for gas controllers (and/or monitors/analyzers): If the equipment includes the detection and measurement of toxic or flammable gases, depending on the target country and the specific application, different standards and/or additional requirements may apply.	
Measurement equipment	IEC 61010-031	Hand-held and hand-manipulated probe assemblies for electrical test and measurement.	Standalone standard (not a particular standard, and not used in conjunction with IEC 61010-1)	
	IEC 61010-2-030	Testing and measuring circuits	Covers all equipment with testing or measuring circuits which are connected for test or measurement purposes to devices or circuits outside the measurement equipment itself. In some cases requirements of -2-030 may be included in other applicable part 2s (example -2-034) in which case it is sufficient to apply only the product specific part 2 which indicates the applicability of the relevant standards in the "introduction" section.	
	IEC 61010-2-032	Current sensors	Covers hand-held and hand-manipulated current sensors Requirements of Part 2-030 have been included in Part 2-032. Equipment within the scopes of Part 2-030 and Part 2-032 are considered to be covered by the requirements of Part 2-032.	Equipment within the scope of both Part 2-032 and Part 2-033, the two standards are to be read in conjunction. Equipment within the scope of Part 2-032, part 2-033 and part 2-034, the three standards are to be read in conjunction.
	IEC 61010-2-033	Hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage	Covers hand-held multimeters and other meters that have a primary purpose of measuring voltage on a live mains. Requirements of Part 2-030 have been included in Part 2-033. Parts of equipment within the scopes of Part 2-030 and Part 2-033 are considered to be covered by the requirements of Part 2-033.	
	IEC 61010-2-034	Measurement Equipment for Insulation Resistance and Test Equipment for Electric Strength	Covers measurement equipment for insulation resistance and test equipment for electric strength which are connected to units, lines or circuits for test or measurement purposes. Requirements of Part 2-030 have been included in Part 2-034. Equipment within the scopes of Part 2-030 and Part 2-034 are considered to be covered by the requirements of Part 2-034.	

Laboratory equipment	IEC 61010-2-010	Laboratory equipment for the heating of materials	Applies where the heating of materials is one of the functions of the equipment. Specifically addresses the hazards associated with equipment incorporating heating systems. This Part 2 is often used together with other Part 2s such as Part 2-101 if the equipment is intended to be used for IVD purpose.	For equipment with heating and cooling functions refer to the introduction section of the Part 2 Standard for guidance on the application of the correct Part 2 Standard (-2-010, -2-011, -2-012): Where the interaction of heating and cooling function results in additional or more severe hazards Part 2-012 applies, otherwise both Part 2-010 and Part 2-011 apply instead.
	IEC 61010-2-011	Refrigerating equipment	Specifically addresses the hazards associated with equipment incorporating refrigerating systems.	
	IEC 61010-2-012	Climatic and environmental testing and other temperature conditioning equipment	Specifically addresses the hazards associated with equipment incorporating both heating and refrigerating systems that interact with each other such that the combined heating and cooling system yield additional or more severe hazards for the two systems than if treated separately. It also addresses the hazards associated with the treatment of materials by other factors like irradiation, excessive humidity, CO_2 and mechanical movement.	
	IEC 61010-2-020	Laboratory centrifuges	Applies to apparatus intended for laboratory use that applies a centrifuging effect to sample materials.	
	IEC 61010-2-040	Sterilizers and washer-disinfectors used to treat medical materials	Covers equipment for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields.	
	IEC 61010-2-051	Laboratory equipment for mixing and stirring	Covers electrically operated laboratory equipment and its accessories for mechanical mixing and stirring, where mechanical energy influences the shape or size or homogeneity of materials and their accessories. Part 2-010 applies in addition if such equipment contains heating elements.	
	IEC 61010-2-061	Laboratory atomic spectrometers with thermal atomization and ionization	Examples include atomic absorption spectrometers, emission flame photometers, atomic fluorescence spectrophotometers, inductively coupled plasma spectrometers, microwave coupled plasma spectrometers and mass spectrometers, all with thermal atomization and ionization (including tubing and connectors which are provided by the manufacturer for connection to external supplies).	
	IEC 61010-2-081	Automatic and semi-automatic laboratory equipment for analysis and other purposes	This type of 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. Excludes IEC 61010-2-101 (IVD) from scope.	
	IEC 61010-2-091	Cabinet X-Ray systems	This equipment may be used in industrial, commercial, and public environments, for example, to inspect materials, to analyze materials, and to screen baggage and is not intended to apply X-radiation to humans or animals.	
	IEC 61010-2-101	In vitro diagnostic (IVD) medical Equipment	This Part 2 applies if intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body.	

Industrial-process measurement, control and automation equipment	IEC 61010-2-201	Control equipment	Specifies the safety related requirements and related tests for control equipment (e.g. programmable controller (PLC), the components of distributed control systems (DCS), I/O devices, human machine interface (HMI). "Control equipment" means any product performing the function of control equipment and/or their associated peripherals. Intended use is the command and control of machines, automated manufacturing and industrial processes. The control equipment in the scope of this Part 2 is considered as component of an overall automated system.	IEC 61010-2-2xx documents are a series of standards for safety of industrial-process measurement, control and automation equipment
	IEC 61010-2-202	Electrically operated valve actuators	Applies for electric actuators and solenoids as applied to valves, intended to be installed in an industrial process or discrete control environment.	
	IEC 61010-2-203 (under development – forecast publication date in 2021)	Industrial communication circuits / ports interconnection	Specifies safety requirement for equipment including industrial communication circuits and communication ports intended to be installed in an industrial process or discrete control environment	
Measurement, control and laboratory equipment	IEC 61010-2-120	Machinery aspects of equipment	"Horizontal" standard which applies to all products in the scope of IEC 61010-1 which may present hazards from the power driven moving parts incorporated in the equipment.	
	IEC 61010-2-130 (Under development - forecast publication date in 2020)	Equipment intended to be used in educational establishments by children	"Horizontal" standard which applies to all products in the scope of IEC 61010-1 which are intended to be used by children in schools and other educational establishments.	

STATUS OF THE IEC 61010 SERIES IN MAJOR MARKETS

General

Amendments to IEC standards become current on the day of publication, and so the logical consequence is that the IEC 61010:2010 Edition 3, including 2016 Amendment 1 should be applied for new designs together with the applicable Part 2 standards. As most changes in the Amendment can be considered minor the impact on equipment previously designed and already evaluated and tested to Edition 3 will, in most cases, be negligible.

The foreword in each applicable Part 2 standard gives information about which edition of IEC 61010-1 shall be used in conjunction. As an example, Part 2-030:2017 states *"This Part is to be used in conjunction with the latest edition of IEC 61010-1. It was established on the basis of the third edition (2010) of IEC 61010-1, including its amendment 1 (2016)".*

Canada & USA

The current (Third) edition of UL 61010-1 and CAN/CSA-C22.2 No. 61010-1-12 was issued in 2012 and revised in 2015, 2016, and 2018. It adopts the IEC text of IEC 61010-1:2012 with national differences. The November 16, 2018 revision was issued to include the adoption of Amendment 1 of IEC 61010-1, and to revise Annex DVE for permanently installed equipment.

OSHA (Occupational Safety & Health Administration) does not list specific editions / revisions for the 61010 series on their List of Appropriate Test Standards under the Nationally Recognized Testing Laboratory Program, and SCC (Standards Council of Canada) lists their accredited test laboratories based on product categories rather than standards. Thus, manufacturers should follow the Standard Update Notices (SUNs) provided by Intertek for their ETL Listed products for effective dates for the above mentioned standards and their revisions.

Note that the NEC (National Electrical Code) and CEC Part I (Canadian Electrical Code Part I) are the basis of federal, state or provincial regulations. Where these codes refer to standards by specific edition, this is being considered in the establishment of effective dates: Whereas CEC Part I, 2018 Edition, lists various CAN/CSA-C22.2 No. 61010 parts as mandatory which are part of the Third edition series; the only reference in the 2017 Edition of the NEC is to UL 61010-201 in an informative Annex. This standard is used in conjunction with the Third Edition of UL 61010-1 and replaces the UL standard for industrial control equipment, UL 508, for programmable logic controllers.

IVD devices are regulated by the US FDA (Food & Drug Administration) and Health Canada. FDA has both IEC 61010-1:2010 Edition 3 and Edition 3 including Amendment 1 (shown as Edition 3.1) on their list of recognized consensus standards; Health Canada's list of recognized standards includes IEC 61010-1:2010 Edition 3 and IEC 61010-2-101:2015.

Europe

European standard EN 61010-1:2010/A1:2019 was approved by CENELEC on 2018 August 06 with the date of withdrawal of the previous version of February 22, 2022, which means that the member countries do have the obligation to implement the standard on a national level. It consists of the text of IEC 61010-1:2010/AMD1:2016 together with common modifications. Annex ZZ lists the relationship between the standard and the safety objectives of the LVD (see below) aimed to be covered.

In order to comply with CE marking legislation, a Technical File must be compiled and be supported by a Declaration of Conformity. Documented evidence shall be provided of how compliance with a particular directive was achieved. This would typically include a test report, drawings, circuit diagrams, etc. Due to the broad scope of the EN 61010 series, which CE-marking directive applies for the specific product depends on its intended used and risks involved:

- Low Voltage Directive (LVD) 2014/35/EU: Applies for equipment which is not an In Vitro Diagnostic Device (IVD), and which does not meet the definition of Machinery in article 2 of the Machinery Directive (MD, see below). For mechanical hazards compliance with the Essential Safety and Health requirements of the MD shall be ensured.
- Machinery Directive (MD) 2006/42/EC: Applies wherever the product falls into the definition of Article 2.
- In rare cases, if equipment uses radio communication, it falls within the scope of the Radio Equipment Directive (RED) 2014/53/EU (and not LVD or MD or IVD).
- In-Vitro Diagnostics Directive (IVDD) 98/79/EC: Currently in transition to IVD Regulation (IVDR) 2017/746 (will apply from 2022 May 26).
- ATEX Directive 2014/34/EU: Applies if the equipment is used in explosive atmospheres

Equipment meeting harmonized standards listed in the Official Journal are presumed to be in conformity with the essential safety requirements of a particular directive. Parts of the EN 61010 series are listed under the low voltage directive and IVD directive as following:

- Currently, only EN 61010-1:2010 (without Amendment 1) is listed under the Low Voltage Directive along with various Part 2s.
- EN 61010-2-101:2002 is listed under the IVD Directive. This standard is used in conjunction with Edition 2 of IEC 61010-1.
- EN 61010-1:2010 (without Amendment 1) is listed also under the ATEX Directive along with various Part 2s.

However, taking the state-of-the-art approach, it is recommended to use more recent versions of the standards including Amendment 1 of EN 61010-1 and EN 61010-2-101:2017.

Note that IEC 61010-2-120 covering machinery aspects has not yet been accepted as a European standard and is also not a standard harmonized under the MD. However, as standards are not mandatory in Europe, manufacturers may use Part 2-120 on a voluntary basis to demonstrate compliance with some of the Essential Health and Safety requirements of the MD.

China

The active Chinese standards are still based on IEC 61010-1 Edition 2 and their related Particular standards as following:

Active China Standard	Corresponding IEC Version	Scope
GB 4793.1-2007	IEC 61010-1:2001	(General) electrical equipment for measurement, control and laboratory use
GB 4793.2-2008	IEC 61010-2-032:2002	Hand-held and hand-manipulated current sensors for electrical test and measurement
GB 4793.3-2008	IEC 61010-2-051:2005	Laboratory equipment for mixing and stirring
GB 4793.4-2001	IEC 61010-2-041:1995	Autoclaves using steam for the treatment of medical materials, and for laboratory processes
GB 4793.5-2008	IEC 61010-2-031:2002	Hand-held probe assemblies for electrical measurement and test
GB 4793.6-2009	IEC 61010-2-010:2005	Laboratory equipment for the heating of materials
GB 4793.7-2008	IEC 61010-2-020:2006	Laboratory centrifuges
GB 4793.8-2008	IEC 61010-2-042:1997	Autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes
GB 4793.9-2013	IEC 61010-2-081:2009	Automatic and semi-automatic laboratory equipment for analysis and other purposes
YY 0648-2008	IEC 61010-2-101:2005	In vitro diagnostic (IVD) medical equipment

The work on newer versions of the standard series has already started, such as for GB 4973.1 (based on IEC 61010-1 Edition 3, not including Amendment 1) and GB 4793.7 (based on IEC 61010-2-020:2016) but so far no clear timeline has been communicated.

IVD products are regulated by NMPA (China National Medical Product Administration), former CFDA (China Food And Drug Administration); for the time being only test reports issued by China national laboratories are being accepted.

Japan

In Japan, only a few parts of the IEC 61010 series have been adopted and published (with modifications) as part of the JIS C 10101- series:

JIS Standard	Corresponding IEC Version	Scope
JIS C 1010-1:2019	IEC 61010-1:2010 (MOD) IEC 61010-1:2010/AMENDMENT 1:2016 (MOD)	(General) electrical equipment for measurement, control, and laboratory use
JIS C 1010-31:2019	IEC 61010-031:2015 (MOD) IEC 61010-031:2015/AMENDMENT 1:2018 (MOD)	Hand-held and hand-manipulated probe assemblies for electrical test and measurement.
JIS C 1010-2-30:2014	IEC 61010-2-030:2010 (MOD)	Testing and measuring circuits
JIS C 1010-2-32:2015	IEC 61010-2-032:2012 (MOD)	Current sensors
JIS C 1010-2-33:2015	IEC 61010-2-033:2012 (MOD)	Hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage
JIS C 1010-2-101:2017	IEC 61010-2-101:2015 (IDT)	In vitro diagnostic (IVD) medical Equipment
JIS C 1010-2-201:2016	IEC 61010-2-201:2013 (IDT)	Control equipment

Japan's PMD (Pharmaceutical and Medical Device) act refers to JIS C10101 and JIS C1010-2-101 only; the 2014 version of JIS C1010-1 can be used.

Taiwan

Taiwan has not published any national standard based on IEC 61010-1 covering the general requirements. The only two Taiwanese standards which currently exist are the following:

- CNS 15449-2 (100年5月4號) referring to IEC 61010-2-041:1995 Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (Note that this standard was replaced by IEC 61010-2-040 in 2005)
- CNS 15449-2-101 (103年3月18號) referring to IEC 61010-2-101: 2002 Particular requirements for in vitro diagnostic (IVD) medical equipment

BSMI (Bureau of Standard, Metrology, and Inspection under the Ministry of Economic Affairs) is the authority responsible for standardization, metrology, and product inspection in Taiwan. BSMI (Taiwan) Certification is voluntary only for products falling in the scope of the IEC 61010 series of standards, the BSMI mark is not required.

Brazil

Brazil has not published national versions of the IEC 61010 series, however, IEC 61010-1 Ed. 3.0 b and various Particular Standards (e.g. IEC 61010-2-040 Ed. 1.0 b and IEC 61010-2-032 Ed. 3.0 b) are referenced in the ABNT (Brazilian Association of Technical Standards) standards catalogue. ABNT is the normative body which is responsible for technical standards in Brazil.

IVD products in Brazil are regulated by ANVISA (Brazilian Health Regulatory Agency). Resolution RDC36/2015 applies to IVD products manufactured in Brazil, and those manufactured abroad, that will be imported to Brazil.

ANVISA Normative Instruction IN 04/2015 has removed INMETRO (National Institute of Metrology Standardization and Industrial Quality) certification requirements for IVD products; they are exempt from complying with IEC 61010-2-101:2002.

IECEE CB Scheme

The IECEE CB Scheme is based on the principle of mutual recognition of test results by its members for obtaining certification or approval at the national level. Which edition (and amendments) to use by manufacturers of medical equipment depends on the national regulatory requirements in each country.

From the IEC point of view, a new edition replaces the old one as soon as it is published; the same applies to Amendment 1 of IEC 61010-1, Edition 3.

Both IEC 61010-1 Edition 3 and Amendment 1 are listed as standards operated in the IECEE on www.iecee.org

Intertek recommends that you consult directly with your electrical testing laboratory to determine which standard edition (and amendment) is currently being accepted in each target country. In some cases it may be necessary to evaluate to more than one edition and/or amendment to ensure acceptance by the recognizing NCBs, as particular standards may have differing transition dates.

REFERENCED STANDARDS AND ADDITIONAL REQUIREMENTS BASED ON THE APPLICATION AND HAZARDS INVOLVED

IEC 61010-1 and the Part 2 standards include a lot of references to other standards which shall be taken into consideration at an early stage, e.g. for components, specific environments, and hazards not addressed in depth in IEC 61010-1. At the same time, for certain applications and depending on the target country(-ies) and certification schemes, manufacturers may have to consider product specific standards which are not part of the IEC 61010 series or referenced by it. Some may, however, point to relevant parts of the IEC 61010 series.

Important requirements manufacturers should be aware of include the following:

Risk Assessment

IEC 61010-1 leaves the manufacturer some flexibility regarding the choice of risk assessment procedures and only gives examples of procedures and references to standards which may be (partly) used, depending on the product application, such as:

- General: IEC 61010-1 Annex J, ISO 14971, SEMI S10-1296, IEC 61508, ISO 14121-1, ANSI B11.TR3.
- Ergonomics: EN 894-2, EN 894-3, SEMI S9

Other established procedures which implement similar risk assessment steps as described in the above standards may also be used.

Functional Safety

With regard to risk assessment, IEC 61010-1 includes a reference to IEC 61508 [Functional safety of electrical/electronic/programmable (E/E/P) electronic safety-related systems] but no detailed requirements; Part IEC 61010-2-201 for control equipment, however, excludes functional safety aspects from its scope.

For equipment in the scope which falls under the definition of “machinery” the typical application of the standards on functional safety is in risk reduction measures undertaken in connection with E/E/P components. In many cases functional safety plays only a partial role in risk reduction, e.g. by monitoring the position of mechanical safety devices, monitoring the functions of redundant electronic systems, etc. The sub-function which is therefore part of risk reduction shall be classified in line with the selected standard, a SIL (Safety Integrity Level) from IEC 61508 or IEC 62061, or a PL (Performance Level) from ISO 13849. This concept is described further in informative Annex J.101 of IEC 61010-2-120 covering the machinery aspects of equipment.

Use in Hazardous Locations

IEC 61010-1 excludes protective measures for explosive atmospheres and refers to IEC 60079 (all parts). This means, for products in the scope of IEC 61010-1, which are used in hazardous locations, both the applicable parts of the IEC 61010 and 60079 series shall be used.

IEC 61010-2-012 has some specific references to requirements of standards in the IEC 60079 series.

Requirements for components and sub-assemblies

Safety critical components and sub-assemblies shall comply with one of the following:

- Applicable safety requirements of a relevant IEC component standard
- Requirements of IEC 61010-1, and any additional safety requirements of the relevant IEC component standard (except for motors and transformers meeting requirements of IEC 61010-1)
- IEC 61010-1, where no relevant component standard exists
- Applicable safety requirements of a non-IEC standard which are at least as high as those of the relevant IEC component standard

Note that additional requirements may apply based on the applicable certification scheme for the end product.

Equipment incorporating sources of optical radiation – Lamps, lamp systems, and laser sources

The 2016 Amendment 1 to IEC 61010-1:2010 added requirements for optical radiation in Clause 12.3 which go beyond those in Edition 3 which covered UV radiation only.

Equipment with lamps and lamp system emitting UV, visible, or infrared radiation, including LEDs, shall not permit unintentional escape of radiation that could cause a hazard. The standard now requires an assessment in according to IEC 62471 (Photobiological safety of lamps and lamp systems) except for sources considered "safe" such as indicator LEDs, computer displays and photographic flash lamps. Lamp and lamp systems in Risk Group 1, 2 or 3 shall be labelled in accordance with IEC TR 62471-2 (Guidance on manufacturing requirements relating to non-laser optical radiation safety) and information provided such as on protective measures.

Equipment employing laser sources shall meet the requirements of IEC 60825-1 (Safety of laser products – Part 1: Equipment classification and requirements). This means it is not sufficient for the laser source (e.g. internal laser module) merely to be classified and marked as per IEC 60825-1; it is required to determine the laser classification of the end product and, depending on the Laser Class, incorporate the required protection means (e.g. interlock switch), markings and documentation.

Batteries

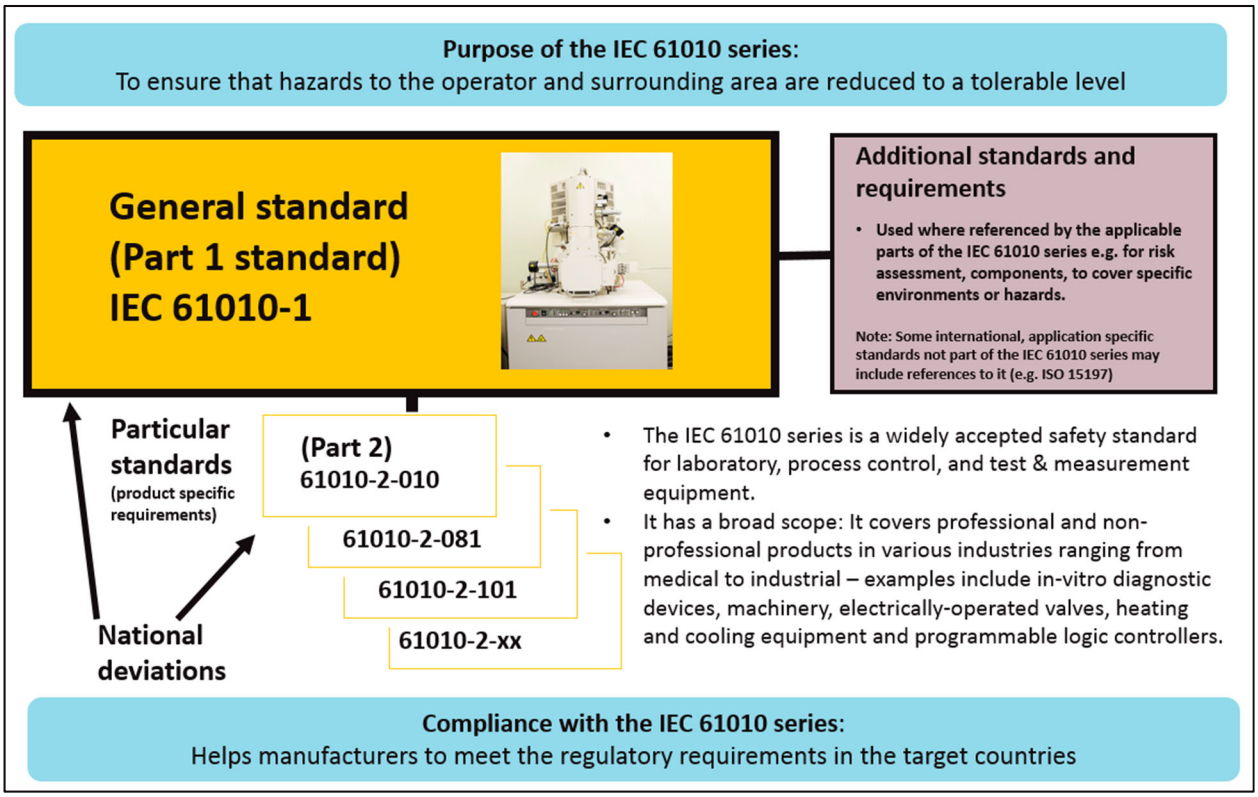
IEC 61010-1 includes requirements for batteries and battery charging. Batteries shall not cause explosion or produce a fire hazard as a result of excessive charge or discharge if installed with incorrect polarity. Also, failure of a single component (e.g. short circuit, open circuit) shall not lead to an explosion or fire hazard.

Although the standard has no specific reference to battery standards such as IEC 62133-2 for secondary lithium batteries or IEC 60086-4 for primary lithium batteries, it is recommended to select suitably certified batteries to the relevant standard to meet the requirements for components as mentioned above, and to ensure the acceptance of the batteries in certification schemes such as the IECEE CB Scheme.

Standards not referenced by, but used in conjunction with IEC 61010-1

When determining the applicability of standards for measurement, control, and laboratory use, manufacturers should not rely solely on the IEC 61010 series but look beyond it to ensure compliance with the relevant requirements in the target countries. One example of an international standard which has been adopted in various countries and published as a national standard which is not a particular standard to IEC 61010-1, but which is used in conjunction is ISO 15197 (In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus).

The 2013 edition states that the requirements in IEC 61010-1 and IEC 61010-2-101 pertaining to safety apply, specifically referencing IEC 61010-1 in regards to protection against electric shock, mechanical hazards and resistance to shock, resistance to heat, resistance to moisture and liquids, protection against liberated gases, explosion and implosion and meter components.



CONCLUSION

The IEC 61010 series, with its broad scope covering products in various industries, is a complex standard which has matured over the years. New Particular (Part 2) standards have been published which are used in conjunction with Edition 3 of the general standard IEC 61010-1, which address the risks specific to the equipment's application and use. Amendment 1 incorporates only minor changes which have not yet been adopted in many countries outside of the EU but should already be considered by manufacturers in new equipment designs.

Intertek will partner with you, providing an interactive approach addressing your concerns via device design review and assessment of the risk management, usability, and software processes to determine their suitability to the 3rd Edition series of standards. We will help you determine the appropriate standards and requirements to ensure acceptance of your products in the targeted markets.

If you have any questions or would like to start a new project or design review, contact your Intertek account manager or project engineer, email icenter@intertek.com, or call us at 1-800-WORLDLAB (1-800-9675352).

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