IEC 61010-2-091

Edition 2.0 2019-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Safety requirements for electrical equipment for measurement, control, and laboratory use –
Part 2-091: Particular requirements for cabinet X-ray systems

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-091: Exigences particulières pour les équipements à rayons X montés en armoire

IEC 61010-2-091:2019-02(en-fr)

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-091: Particular requirements for cabinet X-ray systems

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International Standard IEC 61010-2-091 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This second edition cancels and replaces the first edition published in 2012. It constitutes a technical revision.

This edition includes the following significant changes from the first edition, as well as numerous other changes:

- The scope of the document has been clarified and limited to equipment up to 500 kV.
- Additional marking requirements for X-ray generating assemblies have been added. (5.1)
- Requirements for high-voltage cables used in the X-ray assembly have been added. (6.5)
- Insulation requirements have been added. (6.7)
- Temperature requirements for beam-limiting devices have been added. (10.3)

- Clarification has been provided on PROTECTED EQUIPMENT and PARTIALLY PROTECTED EQUIPMENT, and test methods. (12)
- Requirements for INTERLOCKS have been modified, taking into account functional safety standards. (15)
- Requirements for reasonably foreseeable misuse have been clarified. (16)
- Risk assessment has been made mandatory for specific aspects. (17)

The text of this International Standard is based on the following documents:

FDIS	Report on voting
66/684/FDIS	66/686A/RVD

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.

This document is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) of IEC 61010-1, including its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-091 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for cabinet X-ray systems*.

Clauses of Part 1 that are fully applicable are indicated by the statement "This clause of Part 1 is applicable." Where this Part 2-091 identifies a particular subclause and states "addition", "modification", "replacement", or "deletion", the text of that particular subclause Part 1 is adapted accordingly. Where a particular subclause of Part 1 is not mentioned in this Part 2-091, that subclause applies as far as is reasonable.

In this standard:

a) the following print types are used:
   - requirements: in roman type;
   - NOTES: in small roman type;
   - conformity and tests: *in italic type*;
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.

b) subclauses, figures, and tables 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).

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.

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.

INTRODUCTION

IEC 61010-1 specifies the safety requirements that are generally applicable to all equipment within its scope. For certain types of equipment, the requirements of IEC 61010-1 and its amendments will be supplemented or modified by the special requirements of one, or more than one, particular Part 2s of the standard, which are to be read in conjunction with the Part 1 requirements.

This document has been prepared, based on IEC 61010-1:2010 including its Amendment 1:2016, to specify additional safety requirements for cabinet X-ray systems. It provides additional guidance for construction and assessment of extra high voltage circuits, mechanical HAZARDS and ionizing radiation HAZARDS which can be present in this type of equipment.

This document has been written to provide protection against both radiation HAZARDS from the direct X-ray beam and any scattered X-radiation caused by reflections of the X-ray beam on any part of the equipment or on the sample subjected to X-rays.

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of cabinet X-ray systems.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-091: Particular requirements for cabinet X-ray systems

1 Scope and object

This clause of Part 1 is applicable, except as follows:

1.1 Scope

1.1.1 Equipment included in scope

Deletion:

Delete the first paragraph.

Replacement:

Replace the second paragraph (above items a) to c)) with the following new text:

This part of IEC 61010 specifies particular safety requirements for cabinet X-ray systems, which fall under any of categories a), b) or c) below.

Addition:

Add the two following new paragraphs at the end of the subclause:

Equipment covered by this document can be both PROTECTED EQUIPMENT or PARTIALLY PROTECTED EQUIPMENT, with X-ray generator voltage up to 500 kV.

A cabinet X-ray system is a system that contains an X-ray tube installed in a cabinet, which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and prevent operator access to the radiation beam, during generation of X-radiation.

These cabinet X-ray systems are used in industrial, commercial, and public environments, for example, to inspect materials, to analyse materials, and to screen baggage.

1.1.2 Equipment excluded from scope

Addition:

Add the following new items to the list:

aa) Equipment intended to apply X-radiation to humans or animals;

bb) Equipment incorporating an X-ray tube but not incorporating complete shielding against X-radiation HAZARDS, such as:

- equipment intended to be used within a shielded room which excludes personnel during operation;
- equipment intended to be used with separate portable or temporary shielding;
- equipment intended to produce an emerging beam of X-radiation.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following new text to the end of the first paragraph:

This part of IEC 61010 specifies requirements for the design and methods of construction of cabinet X-ray systems to provide adequate protection for OPERATORS, bystanders, trained service personnel and the surrounding area against unintentionally-emitted X-radiation and from mechanical HAZARDS related to their conveyors.

2 Normative references

This clause of Part 1 is applicable, except as follows:

Addition:

Add the following references to the list:

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

ISO 13849-1, *Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design*

3 Terms and definitions

This clause of Part 1 is applicable, except as follows:

3.2 Parts and accessories

Addition:

Add the following new terms and definitions:

3.2.101
ACCESS PANEL
PROTECTIVE BARRIER or panel which is designed to be removed or opened through the use of a TOOL for maintenance or service purposes to permit access to the interior of the cabinet

3.2.102
APERTURE
opening in the outside surface of the cabinet, other than a PORT, which remains open during generation of X-radiation

3.2.103
DOOR
PROTECTIVE BARRIER which is designed to be movable or opened for routine operation purposes, does not generally require TOOLS to open and permits access to the interior of the cabinet

Note 1 to entry: Inflexible hardware rigidly affixed to the DOOR is considered part of the DOOR.

Note 2 to entry: Access openings intended for the OPERATOR, for removal or re-alignment of samples, are considered as a DOOR.

3.2.104
EXTERNAL SURFACE
outside surface of the cabinet X-ray system, including DOORS, ACCESS PANELS, latches, control knobs and other permanently mounted hardware, the virtual surface across any APERTURE or PORT, and the bottom of the cabinet

3.2.105
PORT
opening in the EXTERNAL SURFACE of the cabinet which is designed to remain open during generation of X-rays, for the purpose of conveying objects into and out of the cabinet or for partial insertion for irradiation of an object with dimensions that do not permit complete insertion into the cabinet

3.2.106
PROTECTED EQUIPMENT
cabinet X-ray system without any APERTURE or PORT, which would allow access to any area with X-radiation

Note 1 to entry: Access can be prevented through INTERLOCK protected DOORS, PORTS, APERTURES or ACCESS PANELS.

3.2.107
PARTIALLY PROTECTED EQUIPMENT
cabinet X-ray system with APERTURE or PORT, allowing access to any area with X-radiation

Note 1 to entry: Access to the X-ray beam or scattered X-radiation could be prevented through a combination of ENCLOSURE and flexible radiation absorbents, for example, one or several curtains containing lead or another radiation absorbing material.

3.2.108
BEAM-LIMITING DEVICE
device to limit the radiation field, such as a collimator, a cone or an APERTURE, intended to restrict the dimensions of X-ray field

3.2.109
INTERLOCK
arrangement of components or devices operating together, intended to prevent a HAZARD or specific operation whenever safety is compromised by access to the interior of the system, operational irregularity or equipment failure

[SOURCE: IEC 62463:2010, 3.11, modified – The term "safety interlocks" has been replaced with "interlock" and the wording "interrupt the generation of X-radiation" has been replaced with "a HAZARD or specific operation".]

4 Tests

This clause of Part 1 is applicable, except as follows:

4.3.2.4 Covers and removable parts

Addition:

Add the following new paragraph at the end of the subclause:

For the test in 12.2.1.101.3, any flexible radiation absorbents used to close the APERTURE or PORT openings for PARTIALLY PROTECTED EQUIPMENT shall remain in their normal closed position.

5 Marking and documentation

This clause of Part 1 is applicable, except as follows:

5.1 Marking

5.1.3 MAINS supply

Addition:

Add the following new text to item c, after the existing paragraph:

The measured power or input current is not to include a periodic short-time (less than 1 min) load that is greater than the average 1 min RMS load. However, when such a value exceeds 125 % of the marked nameplate RATING, it shall be included in the marked RATING of the equipment.

NOTE Transients and initial inrush current are excluded.

Addition:

Add the following new subclause:

5.1.101 Additional markings for cabinet X-ray systems

5.1.101.1 General

The following markings a) to d) shall be provided for cabinet X-ray systems:

a) The equipment shall be marked at the location of each control which may be used to initiate X-radiation, with the text:

"Caution: X-rays generated when activated"

or substantially similar text or adequate symbol;

b) Equipment where the radiation dose is more than 5 µSv/h shall be marked adjacent to each PORT or APERTURE, which is sufficiently large to admit human body parts to the interior of the cabinet, with the text:

"Caution: X-ray hazard. Do not place any
part of the body inside the cabinet when system is activated"

or substantially similar text or adequate symbol.

c) The indicators required by 12.2.1.104 shall be marked "X-ray on", or equivalent text or symbol;

NOTE If a milliamperemeter is used as one of the required indicators, it is marked as specified in 12.101.4, and is not marked "X-ray on".

d) For cabinet X-ray systems designed so that humans may enter the cabinet for specified purposes, permanent markings shall be provided inside the cabinet to describe the function of the signals and controls required by 12.2.1.104 c) and 12.2.1.104 d).

NOTE Specific purposes can be, but are not limited to, service, maintenance or adjustment of settings.

Conformity is checked by inspection.

Suitable symbols or a combination of symbol and text can be used if evaluation per Clauses 16 and 17 has been performed and the symbols are properly explained in the user documentation.

NOTE National regulations can require a nationally accepted language for safety instructions and symbols.

5.1.101.2 BEAM-LIMITING DEVICES

BEAM-LIMITING DEVICES detachable in NORMAL USE by an OPERATOR shall be provided with the following markings:

– those required in IEC 61010-1:2010 and IEC 61010-1:2010/AMD1:2016, 5.1;
– serial designation or individual identification;
– total filtration in terms of quality equivalent filtration.

Conformity is checked by inspection.

5.1.101.3 X-ray tubes

When an X-ray tube is constructed as a component of the cabinet X-ray system, the following is applicable. The markings on the X-ray tube shall remain readable when the X-ray tube is dismantled from the X-ray tube housing. The markings shall enable individual products, series or types to be correlated with their accompanying documents.

X-ray tubes shall be provided with the following markings:

– name or trademark of the manufacturer;
– model or type reference;
– individual identification.

The above markings may be given in the form of a combined designation explained in the accompanying documents.

Conformity is checked by inspection.

The requirements for X-ray tube assemblies apply when the X-ray tube is part of a subassembly and not a stand-alone component.

5.1.101.4 X-ray tube assemblies

When X-ray tube assemblies are constructed as components of the cabinet X-ray system, the following is applicable:

– X-ray tube assemblies shall be provided with the following markings on the outside:
  - name or trademark of the manufacturer;
  - model or type reference;
  - individual identification;
  - nominal X-ray tube voltage for which the X-ray tube assembly is designed;
– and, as applicable, the following additional markings:
  - indication of the polarity of the receptacles for high-voltage cables;
  - permanent filtration.

Conformity is checked by inspection.

5.4 Documentation

5.4.1 General

Replacement:

Replace item d) with the following new text:

d) the information specified in 5.4.2 to 5.4.6 and in 5.4.101;

5.4.3 Equipment installation

Addition:

Add the following new item:

aa) If cooling is necessary for the safe operation of equipment, or a subassembly thereof, the cooling requirements shall be indicated in the documents, as identified in the RISK assessment.

5.4.4 Equipment operation

Addition:

Add the following new items:

aa) in the instructions for use, the loading factors shall be stated as described below. The following combinations and data shall be stated:

- the corresponding nominal X-ray tube voltage together with the highest X-ray tube current obtainable from the equipment when operated at that X-ray tube voltage;
- the corresponding highest X-ray tube current together with the highest X-ray tube voltage obtainable from the equipment when operating at that X-ray tube current;
- the corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electric power in the high-voltage circuit.

The nominal electric power shall be given together with the combination of X-ray tube voltage and X-ray tube current and, if applicable, the loading time.

The range of acceptable X-ray tube current, X-ray tube voltage and load times may be given as a table or a curve showing the dependences.

bb) the instructions for use shall state the maximum symmetrical radiation field of the integrated X-ray source assembly;

cc) the instructions for use shall contain a description of the particular handling and maintenance of any X-ray image receptor.

Replacement:

Replace the conformity statement with:

Compliance is checked by inspection of the instructions for use.

Addition:

Add the following new subclause:

5.4.101 Additional documentation for cabinet X-ray systems

Instructions for the RESPONSIBLE BODY shall include:

a) voltage, current, and, if applicable, duty cycle RATINGS of the X-ray equipment;

b) instructions concerning radiological safety procedures and precautions which may be necessary because of unique features of the equipment;

c) a schedule of maintenance; and

d) a recommendation to consult national authorities to determine any local operational requirements.

Instructions for service personnel shall include:

e) instructions for test after repair or maintenance.

Instructions for installation and commissioning shall also include instructions for assembly, adjustment and tests to ensure that the equipment is safe after it is commissioned.

Conformity is checked by inspection.

6 Protection against electric shock

This clause of Part 1 is applicable, except as follows:

6.5.2 PROTECTIVE BONDING

Addition:

Add the following new subclause:

6.5.2.101 X-ray tube assembly

There shall be electrical continuity between the screen of a fitted high-voltage cable and the ACCESSIBLE metal parts of its receptacle on the X-ray tube assembly.

In addition, high voltage cables, carrying X-ray tube current, ACCESSIBLE by operator or service personnel, shall incorporate a flexible conductive screen having a maximum resistance per unit length of 1 Ω/m covered with a non-conductive material capable of protecting the screen against mechanical damage in NORMAL USE.

Such screens shall be connected to the conductive ENCLOSURE of the high voltage generator and to that of the x-ray tube assembly.

An exception to this requirement are high voltage cables carrying x-ray tube current within a fully enclosed and fully integrated X-ray generator / X-ray tube assembly referred to as a monoblock.

Compliance is checked by visual inspection and by measurement.

Flexible conductive screens shall not be recognized as satisfying a requirement for a protective earth connection between the devices connected by the cable.

6.7 Insulation requirements

6.7.1.5 Requirements for insulation according to type of circuit

Addition:

Add the following new paragraph at the end of the subclause:

Isolation between high voltage circuits in the generator, wiring or X-ray tube and the ACCESSIBLE circuit is to be based on the actual WORKING VOLTAGE stressing the said isolation.

Isolation requirements for any stator and stator circuit used for the operation of any rotating anode of the X-ray tube is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.