

BS EN 61010-2-091:2012
Incorporating corrigendum May 2013



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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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National foreword

This British Standard is the UK implementation of EN 61010-2-091:2012, incorporating corrigendum May 2013. It is identical to IEC 61010-2-091:2012.

The UK participation in its preparation was entrusted to Technical Committee EPL/66, Safety of measuring, control and laboratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Amendments/corrigenda issued since publication

Date	Text affected
31 May 2013	Implementation of CENELEC corrigendum January 2013: Annex ZB inserted

English version

**Safety requirements for electrical equipment for measurement, control
and laboratory use -**

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

(IEC 61010-2-091:2012)

Règles de sécurité pour appareils
électriques de mesure, de régulation et
de laboratoire -
Partie 2-091: Exigences particulières pour
les équipements à rayons x montés en
armoire
(CEI 61010-2-091:2012)

Sicherheitsbestimmungen für elektrische
Mess-, Steuer-, Regel- und Laborgeräte -
Teil 2-091: Besondere Anforderungen für
Röntgengeräteschränke
(IEC 61010-2-091:2012)

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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.

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 66/462/FDIS, future edition 1 of IEC 61010-2-091, prepared by IEC/TC 66 "Safety of measuring, control and laboratory equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61010-2-091:2012.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2013-04-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-07-30

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

This standard covers the Principle Elements of the Safety Objectives for Electrical Equipment Designed for Use within Certain Voltage Limits (LVD - 2006/95/EC).

This Part 2-091 is intended to be used in conjunction with EN 61010-1:2010. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This Part 2-091 supplements or modifies the corresponding clauses in EN 61010-1 so as to convert that publication into the EN standard: *Particular requirements for CABINET X-RAY SYSTEMS*.

Where a particular subclause of Part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

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).

Endorsement notice

The text of the International Standard IEC 61010-2-091:2012 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)
**Normative references to international publications
with their corresponding European publications**

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Addition to Annex ZA of EN 61010-1:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 62061	-	Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems	EN 62061	-
ISO 13849-1	-	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design	EN ISO 13849-1	-

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Annex ZB
(informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC national member.

This European Standard falls under Directive LVD (2006/95/EC).

NOTE (from CEN/CENELEC IR Part 2:2006, 2.17) While standards fall under EC Directives, it is the view of the Commission of the European Communities (O. J. L 59, 1982-03-09) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovich (European Court Reports 1980, p. 3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA-country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

Country	Divergence
France	National legislation Section 1 of the Decree of 2 September 1991, determining technical requirements to be met by X-ray generators, used in industrial radiology, states: <i>"The devices of X-ray generators used in industrial radiology, including accessories, put into service after the publication of this Decree shall comply with the rules set out the date of commissioning by the approved French standard NF C 74-100 concerning Radiology equipment. X-ray apparatus - Construction and tests. or any equivalent standard of a Member State of the European Economic Community "</i>

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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

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 with the following:

This part of IEC 61010 specifies particular safety requirements for CABINET X-RAY SYSTEMS.

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 exclude personnel from the interior during generation of X-radiation.

These CABINET X-RAY SYSTEMS are used in industrial, commercial, and public environments, for example, to inspect materials, to analyze 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:
 - 1) equipment intended to be used within a shielded room which excludes personnel during operation;
 - 2) equipment intended to be used with separate portable or temporary shielding;
 - 3) equipment intended to produce an emerging beam of X-radiation.

1.2.1 Aspects included in scope

Addition:

Add the following text at 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 definitions:

3.2.101

ACCESS PANEL

barrier or panel which is designed to be removed or opened 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

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.

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 a dimension that does not permit complete insertion into the cabinet

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

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

5.1 Marking

Replacement:

Replace the title with:

5.1 Marking, indicators, and annunciators

Addition:

Add the following new subclauses:

5.1.101 Markings for CABINET X-RAY SYSTEMS

The equipment shall be marked at the location of each control which may be used to initiate X-ray generation, with the text, "Caution: X-rays generated when activated", or substantially similar text.

Equipment shall be marked adjacent to each PORT which is sufficiently large to admit human body parts to the direct X-ray beam, with the text, "Caution: X-ray hazard. Do not insert any part of the body when system is activated", or substantially similar text.

The indicators required by 5.1.102 shall be marked "X-ray on", or equivalent.

NOTE 1 If a milliammeter is used as one of the required indicators, it is marked as specified in 5.1.102, and is not marked "X-ray on".

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 5.1.102 c) and 5.1.102 d).

NOTE 2 National regulations may require a nationally-accepted language for safety instructions and markings.

Conformity is checked by inspection.

5.1.102 Indicators and annunciators for CABINET X-RAY SYSTEMS

The equipment shall include all of the following indicators and annunciators.

- a) Two independent means to indicate when X-rays are being generated, located so that at least one indicator is discernible from any location at which the initiation of X-ray generation is possible. The indicators shall be activated only when X-rays are being generated, except that if the X-ray generation period is less than 0,5 s, then the indicator shall be activated for at least 0,5 s. No SINGLE FAULT CONDITION shall disable both indicators. A combination of software, hardware and digital control may be used to generate two redundant "X-ray on" signals.

One, but not both, of these indicators may be a milliammeter labeled to indicate X-ray tube current.

- b) Additional indicators shall be provided as needed to ensure that at least one indicator is visible from each DOOR, ACCESS PANEL, and PORT.

- c) For CABINET X-RAY SYSTEMS which are designed so that humans may enter the cabinet for specified purposes, audible and visual warning signals within the cabinet shall be provided. These signals shall be activated for at least 10 s immediately prior to the first initiation of X-ray generation after closing a DOOR designed so that humans may enter the cabinet. No SINGLE FAULT CONDITION shall disable the audible and the visual indicators at the same time.
- d) For CABINET X-RAY SYSTEMS which are designed so that humans may enter the cabinet for specified purposes, a visible warning signal shall be provided within the cabinet. The indicator shall be activated only when X-rays are being generated, except that, if the X-ray generation period is less than 0,5 s, then the indicator shall be activated for at least 0,5 s.

Conformity is checked by inspection.

5.4.1 General

Replacement:

Replace item d) with the following item:

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

Addition:

Add the following new subclause:

5.4.101 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 generation 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 necessary to keep the equipment in compliance with this standard; and
- d) a recommendation to consult national authorities to determine any local operational requirements.

Instructions for service personnel shall include instructions for test after repair or modification to assure that the equipment remains in compliance with this standard.

Instructions for installation and commissioning shall also include instructions for assembly, adjustment, and test to ensure that the equipment is safe after it is commissioned. See also 12.101.2.

Conformity is checked by inspection.

6 Protection against electric shock

This clause of Part 1 is applicable.

7 Protection against mechanical HAZARDS

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

7.1 General

Addition:

Add a new paragraph and a new Note 101 following the existing note:

Conveyors of CABINET X-RAY SYSTEMS shall comply with the applicable requirements of 7.2 to 7.7, and if any HAZARD is not adequately addressed by those subclauses a RISK assessment (see Clause 17) shall be performed.

NOTE 101 In the United States of America, conveyor systems are required to meet the requirements of ANSI/ASME B20.1.

Replacement:

Replace the conformity statement with:

Conformity is checked as specified in 7.2 to 7.7, and if applicable, Clause 17.

8 Resistance to mechanical stresses

This clause of Part 1 is applicable.

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

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, except as follows:

12.2.1.1 General

Replacement:

Replace the first paragraph and the conformity statement with the following:

CABINET X-RAY SYSTEMS shall meet the requirements of 12.101.

Equipment containing or generating ionizing radiation from radioactive sources, and equipment that generates X-radiation other than in CABINET X-RAY SYSTEMS shall meet the following requirements.

Conformity is checked as specified in 12.101, by inspection of the IEC 60405 compliance documentation, or as specified in 12.2.1.2 or 12.2.1.3, as applicable.

Addition:

Add the following new subclause:

12.101 Ionizing radiation from CABINET X-RAY SYSTEMS

12.101.1 Emitted X-radiation

Radiation emitted from a CABINET X-RAY SYSTEM shall not exceed $0.1 \mu\text{Sv/h}$ at any point 50 mm outside the EXTERNAL SURFACE or at the plane of any APERTURE or PORT.

Conformity is checked by measurements covering the entire outer surface of the cabinet, averaged over cross-sectional areas of 100 mm^2 , with no linear dimension greater than 50 mm, with the CABINET X-RAY SYSTEM operated at those combinations of X-ray tube potential, current, beam orientation, and conditions of scatter which produce the maximum X-ray exposure at each EXTERNAL SURFACE, APERTURE, and PORT with the DOORS and ACCESS PANELS fully closed, and again with the DOORS and ACCESS PANELS in any other positions that permit the generation of X-rays.

12.101.2 Construction

CABINET X-RAY SYSTEMS may be provided with a cabinet bottom or may be designed to be permanently mounted to a floor of a building, whereby the floor of the building becomes the bottom of the system. If the CABINET X-RAY SYSTEM is designed to be permanently mounted to a floor of a building then instructions shall state that radiation measurements must be performed in any dwelling space below the cabinet after it is installed, to ensure that the limit of 12.101.1 is not exceeded, and that additional shielding may be required.

Conformity is checked by inspection.

12.101.3 Controls

The CABINET X-RAY SYSTEM shall be equipped with the following controls:

- a) a key-actuated control to ensure that X-ray generation is not possible with the key removed;
- b) one or more controls to initiate and terminate X-ray generation other than by functioning of an interlock or the MAINS switch;
- c) if designed so that humans may enter the cabinet for specified purposes, a control within the cabinet for preventing and terminating X-ray generation, which cannot be reset, overridden, or bypassed from the outside of the cabinet,
- d) if the system may be located where the public has access, a control to ensure operator presence at the control area before X-ray generation can be initiated or maintained;
- e) if the system may be located where the public has access, a control to terminate the X-ray exposure or the preset succession of exposures at any time.

CABINET X-RAY SYSTEMS designed so that humans may enter the cabinet for specified purposes shall not have any means of initiating X-ray generation from within the cabinet.

Conformity is checked by inspection.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable.

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

Replacement:

Replace the text and conformity statement with the following text:

Interlocks used to protect OPERATORS from HAZARDS other than X-radiation shall prevent the OPERATOR from being exposed to the HAZARD before the HAZARD is removed and shall meet the requirements of 15.2 and 15.3.

Interlocks used only to protect OPERATORS and bystanders against X-radiation HAZARDS shall meet the requirements of 15.101.

Interlocks used to protect both against X-radiation HAZARDS and other HAZARDS shall meet the requirements of 15.2, 15.3, and 15.101.

Conformity is checked by inspection and as specified in 15.2, 15.3, and 15.101, as applicable.

Addition:

Add the following new subclause:

15.101 Interlocks for CABINET X-RAY SYSTEMS

Interlocks for protection against X-radiation shall meet the requirements of 15.3, or either ISO 13849-1 or IEC 62061.

Each DOOR of a CABINET X-RAY SYSTEM shall have a minimum of two independent interlocks. Each of the required interlocks on each DOOR shall be designed to disconnect the power supply circuit to the high-voltage generator, and this operation shall not be dependent on any action other than opening the DOOR.

Each ACCESS PANEL of a CABINET X-RAY SYSTEM shall have at least one interlock or shall require a TOOL to open. The equipment shall be designed so that, following interruption of X-ray generation by the functioning of any interlock, the OPERATOR is obliged to take positive action to resume X-ray generation.

A SINGLE FAULT CONDITION shall not disable more than one required interlock.

Conformity is checked by inspection according to 15.3, ISO 13849-1, or IEC 62061, as applicable.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 Risk assessment

This clause of Part 1 is applicable.

Annexes

All annexes of Part 1 are applicable, except as follows:

<http://www.china-gauges.com/>

Annex L
(informative)

Index of defined terms

Addition:

Add the following new terms to the list:

ACCESS PANEL	3.2.101
APERTURE	3.2.102
DOOR	3.2.103
EXTERNAL SURFACE	3.2.104
PORT	3.2.105

<http://www.china-gauges.com/>

Bibliography

The Bibliography of Part 1 is applicable, except as follows:

Addition:

Add the following entry to the list:

ANSI/ASME B20.1, *Safety standard for conveyors and related equipment*

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BSI Group Headquarters

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