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REDLINE VERSION

INTERNATIONAL STANDARD

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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

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

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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

FOREWORD

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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.

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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
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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.

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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 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 ~~exclude personnel from the interior~~ 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;

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– 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.

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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 ~~a~~ dimensions that do~~es~~ 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.

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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**~~

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~~s~~:

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-~~ray generation~~ 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 ~~direct X-ray beam~~ interior of the cabinet, with the text:

"Caution: X-ray hazard. Do not ~~insert~~ 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 ~~5.1.102~~ 12.2.1.104 shall be marked "X-ray on", or equivalent text or symbol;

NOTE ~~1~~ If a ~~milliammeter~~ milliamperemeter is used as one of the required indicators, it is marked as specified in ~~5.1.102~~ 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 ~~5.1.102~~ 12.2.1.104 c) and ~~5.1.102~~ 12.2.1.104 d).

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

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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 ~~2~~ National regulations ~~may~~ 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.

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~~**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 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;

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– 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 ~~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~~:

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. ~~See also 12.101.2.~~

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:

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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.

6.7.3 Insulation for secondary circuits derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V

6.7.3.1 General

Addition:

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

In this document, high-voltage circuits are secondary circuits comprising components for generation and measurement for power supply of an X-ray tube, such as transformers, voltage-multipliers and voltage-dividers, each rated for working-voltages a.c. above 1 000 V or for (working-voltages) d.c. (above) 1 500 V.

6.7.3.4 Solid insulation

6.7.3.4.1 General

Addition:

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

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In the case of high voltage circuits, the term "solid insulation" is used to describe many different types of constructions, including monolithic blocks of insulating material, insulating subsystems composed of multiple insulating materials, including insulating liquids and insulating castings, organized in layers or otherwise.

Conformity is checked by the 6.8.101 compliance test for high-voltage circuits.

6.8 Procedure for voltage tests

6.8.3.1 The a.c. voltage test

Replacement:

Replace the first sentence by the following sentence:

The voltage tester shall be capable of maintaining the test voltage throughout the test within ±5 % of the specified value.

Addition:

Add the following new subclause:

6.8.101 Procedure for voltage tests of high voltage circuits of X-ray equipment

The high-voltage circuit of the equipment is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s ± 2 s to the full value, which is maintained in intermittent mode and in continuous mode per Table 101.

Table 101 – Durations of high voltage strength test

High-voltage circuits tested in:	Duration
Intermittent mode	3 min
Continuous mode	15 min

The test for the high-voltage circuit shall be made with a test voltage of:

– for nominal X-ray voltage less than 200 kV, 1,1 times the nominal X-ray tube voltage of the equipment; or

– for nominal X-ray tube voltage of the equipment equal to or exceeding 200 kV, the nominal X-ray tube voltage plus 20 kV.

The above test can be conducted on the system as a whole or on the separate parts individually.

For high-voltage generators intended for operation in both intermittent mode and continuous mode, and in which the nominal X-ray tube voltage for continuous mode does not exceed 80 % of that for intermittent mode, the test voltage for the high-voltage circuit shall be that of the intermittent mode, and the test shall be carried out in that mode only.

If during the dielectric strength test, there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

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During the dielectric strength test, slight corona discharges in the high-voltage circuit are to be disregarded.

High-voltage generators or subassemblies thereof, which are integrated with an X-ray tube assembly, are to be tested with an appropriately loaded X-ray tube. If such high-voltage generators do not have separate adjustment of the X-ray tube current, the duration of the dielectric strength test is to be reduced to such an extent that the allowable X-ray tube load at the increased X-ray tube voltage will not be exceeded.

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.~~

NOTE National regulations for conveyor systems can additionally apply. EXAMPLE: ASME B20.1, ANSI/ASME B20.1 for the United States of America.

Replacement:

Replace the existing conformity statement with following new text:

Conformity is checked ~~as specified~~ in accordance with the specifications of 7.2 to 7.7 and, if applicable, of 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, except as follows:

Addition:

Add the following new subclauses:

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10.1.101 Protection against excessive temperatures of X-ray tube assemblies

Where easily ACCESSIBLE EXTERNAL SURFACES of X-ray tube assemblies attain temperatures exceeding those in Table 19, protective means shall be provided to prevent the OPERATOR from contact with such parts in NORMAL USE.

NOTE Protective means can be ENCLOSURE or other barriers preventing access.

Compliance is checked by test of integrity of such means and by inspection of instructions for use.

10.1.102 Protection against excessive temperatures of BEAM LIMITING DEVICES

BEAM-LIMITING DEVICES incorporating a light field-indicator shall be provided with one of the following means to reduce the possible temperature rise occurring if the lamp remains energized while the BEAM-LIMITING DEVICES are covered with drapes or other material, reducing the normal heat dissipation:

a) an overtemperature protection device preventing the lamp from being energized if the allowable maximum temperature of any EXTERNAL SURFACES of the BEAM-LIMITING DEVICES has exceeded the limits of Table 19;

b) a time-limiting device preventing the lamp from remaining energized for a period exceeding 2 min after the most recent action by the OPERATOR to energize it. The manufacturer's instructions shall provide details of required externally connected time-limiting switch;

c) a statement in the manufacturer's instructions giving details of the time-limiting switch to be externally connected to perform the function described in item b) above.

Compliance is checked by inspection

11 Protection against HAZARDS from fluids and solid foreign objects

This clause of Part 1 is applicable.

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

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

Replace 12.2 of Part 1 with the text below.

Replacement:

12.2 Equipment producing ionizing radiation

12.2.1 Ionizing radiation

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.~~

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~~*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.*~~

Equipment containing or generating ionizing radiation (from either radioactive sources or X-radiation) shall not create a HAZARD in normal or SINGLE FAULT CONDITION.

NOTE 1 See IEC 62598 for further information on the requirements for equipment which utilizes ionizing radiation.

NOTE 2 For X-ray and gamma radiation: 1 µSv/h = 0,1 mR/h and 5 µSv/h = 0,5 mR/h.

NOTE 3 Equipment that emits ionizing radiation is regulated by health authorities in most countries. These regulations often address both the emissions of radiation from the equipment and the cumulative dose of radiation received by the workers and others in the vicinity of the equipment. See the Ionizing Radiation Directive (2013/59/EURATOM) or USA 29 CFR 1910.1096 as examples of these regulations.

Conformity is checked by inspection as specified in 12.2.1.101 to 12.2.1.104.

Addition:

Add the following new subclauses:

~~**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 5 µSv/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 1 000 mm², 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.*~~

12.2.1.101 Limits for emitted X-radiation of cabinet X-ray systems

12.2.1.101.1 General

The ambient dose equivalent rate $H^*(10)$ (IEC 60050-395:2014, 395-05-43) emitted from a cabinet X-ray system shall not exceed 5 µSv/h at any point 50 mm outside the EXTERNAL SURFACE or at the plane of any APERTURE or PORT.

The measurements shall be conducted at the maximum available voltage of any high-voltage generator, or highest possible voltage in fault condition

Conformity is checked by the measurements of 12.2.1.101.2 or 12.2.1.101.3, as applicable.

NOTE Specifications for radiation measurement equipment can be found in IEC 60846-1.

12.2.1.101.2 Measurement of emitted X-radiation from PROTECTED EQUIPMENT

Radiation is measured covering the entire EXTERNAL SURFACE of the cabinet, averaged over cross-sectional areas of 1 000 mm², 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.

Measurement is conducted 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.

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12.2.1.101.3 Measurement of emitted X-radiation from PARTIALLY PROTECTED EQUIPMENT

Radiation is measured covering the entire EXTERNAL SURFACE of the cabinet, averaged over cross-sectional areas of 1 000 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.

Measurement is conducted 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, except any flexible radiation absorbents used to close any APERTURE or PORT, which shall remain in their normal closed position.

For this measurement, a scatter body shall be used that represents the typical scanned objects. As in the case of baggage inspection systems, the scanned objects vary considerably in size, content and material, a standardized polyoxymethylene (POM) scatter body shall be used (see Figure AA.1 in Annex AA). The scatter body shall be positioned in the middle of the belt and in the center of the beam.

For multiple beam systems, it shall be ensured that all beams hit a scatter body by using one scatter body for each beam or positioning one scatter body in several beams where possible.

~~12.101.2~~ 12.2.1.102 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 located below the cabinet after it is installed, to ensure that the limit given in 12.2.1.101.1 is not exceeded, and that additional shielding may be required.

Conformity is checked by inspection.

~~12.101.3~~ 12.2.1.103 Controls

The cabinet X-ray system shall be equipped with the following controls, ACCESSIBLE to the OPERATOR:

a) a key-actuated control to ensure that X-~~ray generation~~ radiation is not possible with the key removed;

b) one or more controls to initiate and terminate X-~~ray generation~~ radiation other than by the 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~~ radiation, 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~~ radiation 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 pre-set 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~~ radiation from within the cabinet.

Any signal from these X-ray systems may be processed remotely from the device itself. For the purpose of these requirements, the OPERATOR is considered to be the person supervising the use close to the X-ray system, and not the person processing the images.

Conformity is checked by inspection.

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12.2.1.104 Indicators and annunciators for cabinet X-ray systems

The equipment shall include indicators and annunciators described in 12.2.1.104 a) and b), and, as applicable, the indicators and annunciators described in 12.2.1.104 c) and d).

a) Two independent means to indicate when X-rays are being generated, located so that at least one indicator can be seen 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 indicating means. 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 milliamperemeter labelled to indicate X-ray tube current.

   NOTE When one X-ray indicator mounted on equipment can be seen from all sides of the equipment, the second means to indicate can be part of the control display.

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

Additionally, for cabinet X-ray systems which are designed so that humans may enter the cabinet for specified purposes, the warning signals specified in c) shall be provided:

c) visual warning signals shall be provided within the cabinet when X-rays are being generated. 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.

Additionally, for cabinet X-ray systems which are designed so that humans may enter the cabinet for specified purposes, if any OPERATOR positions are so located such that there is no direct view into the complete cabinet or places exist within the cabinet which are not visible to the OPERATOR at the intended control position, the following additional signals shall be provided:

d) an audible and visual warning signal shall be provided within the cabinet when the X-ray generator of the cabinet X-ray system has been enabled.

   These signals shall be activated for at least 10 s immediately prior to the first possible initiation of X-ray generation. At least one warning signal shall remain active for as long as the X-ray generator is enabled. No SINGLE FAULT CONDITION shall disable the audible and the visual indicators at the same time.

NOTE 1 "Enter" means that the complete body steps into the cabinet, such that a DOOR or ACCESS PANEL can be completely shut.

NOTE 2 Specific purposes can be, but is not limited to, service, maintenance or adjustment of settings.

NOTE 3 Direct view can be, but is not limited to, direct visual or through dedicated monitors.

Conformity is checked by inspection and by evaluation of the RISK assessment documentation.

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, except as follows:

Addition:

Add the following new subclauses:

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14.101 X-ray tube assembly

For any manufacture-specified connected X-ray tube assembly, equipment shall be so designed that the X-ray generator cannot deliver a voltage greater than the nominal RATED voltage for any part of the X-ray tube or X-ray tube assembly concerned, in intended use and in REASONABLY FORESEEABLE MISUSE.

Conformity is checked by inspection, with any user accessible settings for intended use and in REASONABLY FORESEEABLE MISUSE.

14.102 Safety-related control systems

Failure of a safety-related control system using microprocessors and other software control devices shall not cause a HAZARD.

NOTE 1 This requirement can be achieved by redundancy or diversity.

NOTE 2 Further guidance on safety-related control systems using microprocessors and other software controlled devices is given in ISO 13849-2, IEC 61508-3, IEC 62061 and IEC 62304.

If a battery is required to ensure safe operation of any microprocessor, no HAZARD shall arise as a result of loss of this power.

Conformity is checked by inspection, RISK assessment, function of the circuit under evaluation and, in case of doubt, by application of SINGLE FAULT CONDITIONS.

15 Protection by INTERLOCKS

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

15.1 General

Replacement:

Replace the existing text and conformity statement with the following new text:

INTERLOCKS used to protect OPERATORS and any bystander from HAZARDS shall be evaluated by a RISK reduction method. As a result of this, INTERLOCKS may have an appropriate safety integrity level (SIL) or performance level (PL).

NOTE See ISO 12100, and IEC 62061 or ISO 13849-1 for more information.

IAEA and WHO have published the following maximum radiation exposure recommendations:

- 1 mSv effective doses per year for non-occupational exposure.
- 20 mSv effective doses per year for general occupational exposure.
- 50 mSv effective doses per year for general occupational exposure, where 5 year doses are limited to 100 mSv.
- 500 mSv effective doses per year for specific exposure of extremities such as hands or feet.

Lower effective doses are recommended for OPERATORS or bystanders below 18 years of age, as well as for a female worker who is pregnant or breastfeeding. See Annex BB for dose limit recommendations for occupational radiation.

~~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.~~

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

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

Interlocks used only to protect ~~both~~ OPERATORS or bystanders against ~~X-radiation HAZARDS and~~ other HAZARDS shall meet the requirements of 15.2 and 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.*~~

15.101 Availability

15.101.1 Exception

For cabinet X-ray systems that satisfy all the limitations in a) to d), the INTERLOCK system for protection against X-radiation may be according to 15.2 and 15.3 instead of 15.101.2.

a) Access to the X-radiation beam area is protected through two separate independent redundant INTERLOCK circuits;

b) Each of the two separate INTERLOCKS shall meet the requirements of 15.2 and 15.3;

c) The area where the device is located has a physical access restriction, limiting potential ionizing radiation exposure to the OPERATOR only; and

d) A failure of INTERLOCK circuits shall be detectable or checked by periodical inspection of the equipment. The radiation exposure to the OPERATOR until that failure is detected shall be estimated based on the usage of equipment and RISK assessment.

   In case of a failure of both INTERLOCK circuits, the radiation exposure to the OPERATOR shall not exceed:

   – 250 µSv accumulated radiation exposure with a maximum of 25 µSv/h for general exposure;

   – 5 mSv accumulated radiation exposure with a maximum of 100 µSv/h where only the hands or feet of the OPERATOR may be exposed.

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Conformity is checked by inspection and by evaluation of the RISK assessment documentation.

15.101.2 Safety levels

Any safety-related control system on any DOOR or ACCESS PANEL shall be designed to disconnect the power supply circuit to the high-voltage generator, or to remove through other means any X-radiation in the ACCESSIBLE area of the cabinet. This operation shall not be dependent on any action other than opening the DOOR or removing the ACCESS PANEL.

a) Each DOOR of a cabinet X-ray system shall be supervised by a safety-related control system which contains at least one INTERLOCK. The safety-related control system shall have at least PL_r d (Category 3) according to ISO 13849-1, or SIL 2 according to IEC 62061, or a comparable degree of safety based on another internationally recognized functional safety standard.

b) Each ACCESS PANEL of a cabinet X-ray system shall be supervised by a safety-related control system which contains at least one INTERLOCK. The safety-related control system shall have at least PL_r c (Category 2) according to ISO 13849-1, SIL 1 according to IEC 62061, or a comparable performance based on another internationally recognized standard.

In the event that the RISK reduction method demands higher functional safety, the safety levels shall be increased accordingly.

NOTE 1 Means to remove X-radiation can be for example the shutter in the cabinet X-ray system or a grid in the X-ray tube.

NOTE 2 National regulations can require a minimum of two INTERLOCKS at each DOOR of a cabinet X-ray system. National regulations can also state that one, but not both, of the required INTERLOCKS must be such that DOOR opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection cannot be dependent upon any moving part other than the DOOR.

The equipment shall be designed so that, following interruption of X-radiation by the functioning of any INTERLOCK, the OPERATOR is obliged to take positive action to resume X-radiation.

A SINGLE FAULT CONDITION shall not disable the required safety-related control systems.

Conformity is checked by inspection in accordance with ISO 13849-1, IEC 62061, or other internationally recognized standards providing equivalent functional safety, as applicable.

16 HAZARDS resulting from application

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

16.1 REASONABLY FORESEEABLE MISUSE

Replacement:

Replace the existing text and conformity statement with the following new text:

The equipment shall comply with the requirements of this document during NORMAL USE, including mistakes, lapses, slips or use of a product or system in a way not intended by the supplier, but which can result from readily predictable human behaviour. Such acts to consider would include well-meant optimization or readily available shortcuts.

No HAZARDS shall arise, through readily available adjustments, knobs, or other software-based or hardware-based controls that are set in a way not intended, or not described in the instructions.

Reckless use, unqualified use or use outside the specifications given by the manufacture is not considered as part of this document. Similar, intended acts or intended omission of an act by the

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OPERATOR of equipment as a result of conduct that is beyond any reasonable means of risk control by the manufacturer are similarly excluded from the scope of this document.

Other possible cases of REASONABLY FORESEEABLE MISUSE that are not addressed by specific requirements in this document shall be addressed by RISK assessment (see Clause 17).

Conformity is checked by inspection and by evaluation of the RISK assessment documentation.

17 RISK assessment

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

Replacement:

Replace the existing first paragraph with the following new text:

If examination of the equipment shows that HAZARDS not fully addressed in Clauses 6 to 16 (see 1.2.1) might arise, then RISK assessment is required. It shall be carried out and documented to achieve at least a TOLERABLE RISK by an iterative process covering analysis, evaluation and RISK reduction.

RISK assessment is required for the following aspects:

– physical access to direct X-radiation for any PARTIALLY PROTECTED EQUIPMENT;
– emitted X-radiation where people other than the trained personnel can be exposed to such radiation.
– cabinet x-ray systems intended to be used with flammable fluids or with containers or flasks with hazardous or toxic fluids.

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Annexes

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

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Annex L
(informative)

Index of defined terms

Addition:

Add the following terms to the list:

ACCESS PANEL 3.2.101
APERTURE 3.2.102
BEAM-LIMITING DEVICE 3.2.108
DOOR 3.2.103
EXTERNAL SURFACE 3.2.104
INTERLOCK 3.2.109
PORT 3.2.105
PARTIALLY PROTECTED EQUIPMENT 3.2.107
PROTECTED EQUIPMENT 3.2.106

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