IEC 61331-3

Edition 2.0 2014-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical – Partie 3: Vêtements et lunettes de protection radiologique, écrans de protection pour le patient

IEC 61331-3:2014-05(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX U

ICS 11.040.50

ISBN 978-2-8322-1564-7

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

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FOREWORD

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International Standard IEC 61331-3 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 61331-3, published in 1998. It constitutes a technical revision. This second edition has been adapted to apply to the present technology. It includes a requirement to use a better method for the determination of attenuation properties over a broader and more clinically relevant range of RADIATION QUALITIES appropriate to the use of the devices. It also covers three additional protective devices, THYROID COLLARS, PROTECTIVE EYEWEAR and PROTECTIVE APRONS FOR DENTAL USE.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/938/FDIS	62B/944/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– requirements and definitions: roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 61331 series, published under the general title *Protective devices against diagnostic medical X-radiation,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 3: Protective clothing, eyewear and protective patient shields

1 Scope

This part of IEC 61331 applies to PROTECTIVE DEVICES such as PROTECTIVE CLOTHING and EYEWEAR for the protection of persons against X-RADIATION up to 150 kV, during RADIOLOGICAL examinations and interventional procedures.

NOTE PROTECTIVE DEVICES are not intended by themselves to provide complete protection of persons, but are used to reduce the dose to persons where other methods of protection against X-RADIATION are insufficient or not applicable.

This standard deals with:

– general requirements on the ACCOMPANYING DOCUMENTS, on design and on materials used;
– sizing, particular design features, minimum ATTENUATION properties of materials, marking and standardized forms of statements of compliance with this standard.

It covers PROTECTIVE CLOTHING mainly for the protection of the OPERATOR, such as:

– PROTECTIVE APRONS;
– THYROID COLLARS;
– PROTECTIVE GLOVES;
– PROTECTIVE MITTENS;
– PROTECTIVE EYEWEAR;

and PROTECTIVE DEVICES for the protection of the PATIENT, such as:

– PROTECTIVE GONAD APRONS;
– SCROTUM SHIELDS;
– OVARY SHIELDS;
– SHADOW SHIELDS;
– PROTECTIVE APRONS FOR DENTAL USE.

The latter group of PROTECTIVE DEVICES is intended to be used during RADIOLOGICAL examinations to minimize the effects of IRRADIATION on the reproductive organs particularly with regard to genetic damage.

2 Normative references

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.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD 1:2012

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61331-1:2014, *Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials*

EN 340:2003, *Protective clothing – General requirements*

EN 13402-3, *Size designation of clothes – Part 3: Measurements and intervals*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and the following apply.

3.1
AREA DENSITY
W_s

minimum mass per unit area of the protective material used to provide the required LEAD EQUIVALENT of the device, at all of the stated test values of X-RAY TUBE VOLTAGES

Note 1 to entry: AREA DENSITY is expressed in SI units as $kg \cdot m^{-2}$.

3.2
PROTECTIVE APRON FOR DENTAL USE
protective apron worn by the PATIENT to protect the region of the upper torso during RADIOLOGICAL dental procedures

Note 1 to entry: Such an apron may have an accompanying THYROID COLLAR, separate or attached.

3.3
PROTECTIVE EYEWEAR
protective device made of transparent material to protect the eyes

3.4
PROTECTIVE GONAD APRON
protective apron worn by the PATIENT to protect the region of the gonads as an alternative to the use of a SCROTUM SHIELD or an OVARY SHIELD

Note 1 to entry: See also rm-64-05 of IEC TR 60788:2004.

3.5
PROTECTIVE MITTEN
protective glove with open palm and separated thumb used where full perception of touch is essential

3.6
SHADOW SHIELD
protective device to intercept the radiation beam in the areas of the gonads

Note 1 to entry: A SHADOW SHIELD is to be used when a SCROTUM SHIELD and an OVARY SHIELD cannot be used.

3.7
THYROID COLLAR
protective device to cover the thyroid gland

4 General

4.1 ACCOMPANYING DOCUMENTS

PROTECTIVE DEVICES shall not be provided without ACCOMPANYING DOCUMENTS.

The ACCOMPANYING DOCUMENTS shall contain information on the following:

a) identification of the items of PROTECTIVE DEVICE(S) to which they apply, by reference to type or to individual items, as appropriate;
b) description of all markings on the items, with explanation of their meanings;
c) sizing information, in compliance with EN 340:2003 where appropriate, enabling garment label size information to be correlated with body size, where such information is not fully available on the garment label or marking itself;
d) instructions for use, which shall contain:
    1) recommendations for storage when not in use;
    2) recommendations for methods and materials to be used for cleaning and disinfection;
    3) recommended method and frequency of periodic inspection by the OPERATOR in order to verify the maintenance of ATTENUATION properties;
    4) particulars of compliance with this standard.

Any information included in the ACCOMPANYING DOCUMENTS that is particularly intended to be read by the PATIENT, shall be repeated in a separate part containing all such information.

4.2 Language of the ACCOMPANYING DOCUMENTS

This standard contains no requirements concerning the language(s) in which the ACCOMPANYING DOCUMENTS provided are to be written.

Attention is drawn to the fact that when the ACCOMPANYING DOCUMENTS are written in a language other than that in which they were originally drafted and approved by the MANUFACTURER of the PROTECTIVE DEVICES, these documents shall be checked carefully by an expert who, wherever possible, should be authorized by the MANUFACTURER to act in that capacity.

The ACCOMPANYING DOCUMENTS shall state the language(s) in which they were originally drafted, approved or supplied by the MANUFACTURER and shall give a reference identifying at least one original version.

4.3 General requirement on marking

PROTECTIVE DEVICES shall be marked so that their correlation to the pertaining ACCOMPANYING DOCUMENTS is ensured.

4.4 Design

4.4.1 PROTECTIVE DEVICES for the protection of OPERATORS

PROTECTIVE DEVICES for the protection of OPERATORS should be so designed that they can be put on and taken off without assistance.

4.4.2 PROTECTIVE DEVICES for the protection of the PATIENT

PROTECTIVE DEVICES for the protection of the PATIENT shall be designed so that they can be easily applied, and they should be designed so that they can be properly placed and, where necessary, fixed by the PATIENTS themselves.

4.5 Materials

4.5.1 Materials effecting ATTENUATION

The materials effecting the ATTENUATION shall be homogeneously distributed and should contain elements of an atomic number higher than 47.

4.5.2 Cleaning

All outer and inner accessible surfaces of PROTECTIVE DEVICES shall be suitable for cleaning and disinfection.

4.5.3 Touchable surfaces

It shall not be possible to touch, in NORMAL USE, uncovered or uncoated surfaces of metal powders or other attenuating elements or compounds.

5 PROTECTIVE APRONS and THYROID COLLARS

5.1 General

NOTE 1 PROTECTIVE APRONS and THYROID COLLARS are intended to be worn by persons who are present in the EXAMINATION ROOM during RADIOLOGICAL examinations with or without interventional procedures. They are intended primarily to protect the main part of the body of the OPERATOR. To protect the complete body, additional protective devices are useful, for example, PROTECTIVE EYEWEAR and helmets.

For the purpose of this standard, four different categories of PROTECTIVE APRONS are defined:

– light-duty PROTECTIVE APRONS;
– heavy-duty PROTECTIVE APRONS;
– light-duty closed PROTECTIVE APRONS;
– heavy-duty closed PROTECTIVE APRONS.

NOTE 2 Light-duty PROTECTIVE APRONS can be worn for example in the operating theatre and in the gypsum room, or if the SIGNIFICANT ZONE OF OCCUPANCY is protected against STRAY RADIATION by other PROTECTIVE DEVICES, for example fixed on the X-RAY EQUIPMENT.

5.2 Design

PROTECTIVE APRONS shall consist of one or more layers of protective material and shall be designed to cover the front part of the body from the throat down to at least the knees, the entire breastbone and the shoulders.

The width of the material on each shoulder shall be not less than 8 cm for persons having the minimum chest girth of 76 cm (according to EN 340:2003) and shall be graded as chest girth increases.

Unprotected stitch, or other, holes fixing parts together shall not be allowed on the front of a PROTECTIVE APRON.

NOTE 1 X-RADIATION through stitch holes fixing the parts together on the back or sides is not considered, because of the orientation of the OPERATOR'S front towards the source of RADIATION.

Closed PROTECTIVE APRONS shall be designed to cover, additionally:

– the sides of the body from not more than 10 cm below the armpit to the knees.
– the back down to the knees.

Closed PROTECTIVE APRONS should be designed to permit ventilation. For this purpose, overlapping fastenings at the sides, the openings of which point towards the back, or a fastening leaving uncovered a vertical slit in the middle of the back may be provided.

NOTE 2 PROTECTIVE APRONS can consist of two overlapping pieces, a vest and a skirt.

Closed PROTECTIVE APRONS may have overlapping panels with fastenings at the front. Where such overlapping panels provide only partial overlap, each front panel shall have the LEAD EQUIVALENT required under 5.3. Where such panels fully overlap, side to side, effecting full protection to the whole front of the body, each front panel may be half the LEAD EQUIVALENT required under 5.3.

THYROID COLLARS shall be designed to cover the front half of the neck, including the thyroid gland, and should extend from under the jaw down to the neckline of the protective apron. THYROID COLLARS may be sewn on the apron or separate. If separate they shall have a full neckband with fastening at the back.

5.3 Materials

The protective material as well as any fabric covering and binding shall be flexible.

a) The LEAD EQUIVALENT of light-duty PROTECTIVE APRONS shall be not less than 0,25 mm Pb over their entire area.
b) The LEAD EQUIVALENT of heavy-duty PROTECTIVE APRONS shall be not less than 0,35 mm Pb for the front section, and not less than 0,25 mm Pb for the remaining parts.
c) The LEAD EQUIVALENT of light-duty closed PROTECTIVE APRONS shall be not less than 0,25 mm Pb over their entire area.
d) The LEAD EQUIVALENT of heavy-duty closed PROTECTIVE APRONS shall be not less than 0,35 mm Pb for the front section, and not less than 0,25 mm Pb for the remaining parts.
e) The LEAD EQUIVALENT of THYROID COLLARS shall be not less than 0,35 mm Pb.

The LEAD EQUIVALENT shall be determined as described in IEC 61331-1, by the inverse broad beam geometry method for the SPECIFIED range of RADIATION QUALITIES, 50 kV, 70 kV, 90 kV and 110 kV, according to 5.5 of IEC 61331-1.

NOTE PROTECTIVE APRONS and THYROID COLLARS are used for protection against SCATTERED RADIATION and are tested in the 50 kV to 110 kV TUBE VOLTAGE RANGE. However such devices and materials are useful in SCATTERED RADIATION from primary x-ray beams with TUBE VOLTAGES 60 kV to 120 kV because the scattered spectra of these better match those of primary beams having TUBE VOLTAGES 10 kV less.

Where heavy-duty, or heavy-duty closed PROTECTIVE APRONS or THYROID COLLARS are worn for RADIOLOGICAL examinations or in procedures where there is exposure to higher energy radiation, greater than 125 kV, for example in “in-room CT assist” procedures, such PROTECTIVE APRONS should also meet or exceed the LEAD EQUIVALENT values for radiation quality 150 kV, and be marked or labelled accordingly.

5.4 Dimensions

PROTECTIVE APRONS shall be sized to fulfil the design criteria of 5.2, and should be sized in accordance with EN 13402-3. The width of the light-duty and heavy -duty PROTECTIVE APRONS, and the width of the front area of light-duty and heavy-duty closed PROTECTIVE APRONS, shall be at least 60% of the larger of the chest, waist or hip circumference of the body size referenced in EN 13402-3.

5.5 Marking

PROTECTIVE APRONS and THYROID COLLARS shall carry the information called for under items a) to f) in Table 1.

The information shall be marked clearly and permanently, should be on a label and shall include the following:

Table 1 – Information and examples for marking
PROTECTIVE APRONS and THYROID COLLARS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Letter designating the type of PROTECTIVE APRON, namely L (light-duty), H (heavy-duty), LC (light-duty closed) or HC (heavy-duty closed).	L, H, LC or HC
c) Value(s) of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres, as follows: – for all PROTECTIVE APRONS, and THYROID COLLARS , the value applying to the front section – and, if different, the value applying to the back section.	 mm Pb 0,35(front) mm Pb 0,25(back)
d) X-RAY TUBE VOLTAGE range used for the determination of the values of the LEAD EQUIVALENT, appended to the marking given in accordance with item c), by adding an oblique stroke followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts. For PROTECTIVE APRONS designed for higher energy use, to 150 kV (5.3).	 50 kV - 110 kV 50 kV - 150 kV
e) AREA DENSITY, W_S, the minimum mass per unit area in kg.m^{-2}, required to provide the value of LEAD EQUIVALENT stated in (c) above, at X-RAY TUBE VOLTAGE range shown in (d)	 W_S 4,60
f) The size and length of the PROTECTIVE APRON, which shall directly on the label, or indirectly through ACCOMPANYING DOCUMENTS, enable correlation to the body dimensions which should be referenced to EN 13402-3, by pictogram referenced under EN 340, or MANUFACTURER'S sizing dimension tables.	
g) Reference to this standard, given as "IEC 61331-3:2014 ".	

5.6 Statement of compliance

If compliance of a PROTECTIVE APRON with this standard is to be stated, it shall be indicated, as applicable, according to the following example:

Heavy-duty protective apron xyz[1] H[2] Pb 0,35[3]/50 – 110[4] 4,60[5] IEC 61331-3:2014[6].

1) name or trade mark of MANUFACTURER or supplier;

2) for heavy-duty PROTECTIVE APRON;

3) LEAD EQUIVALENT;

4) X-RAY TUBE VOLTAGE range;

5) AREA DENSITY;

6) year of publication of this standard.

6 PROTECTIVE GLOVES

6.1 General

PROTECTIVE GLOVES are intended primarily to be worn by the OPERATOR during those RADIOLOGICAL examinations or interventional procedures in which the hands and forearms need to be protected whilst in the RADIATION BEAM or in high intensities of STRAY RADIATION.

6.2 Design

PROTECTIVE GLOVES shall cover the entire hand, without gaps, and at least half of the forearm. They should allow washable inner gloves to be worn.

PROTECTIVE GLOVES shall be designed so that the thumb is enclosed separately. The other fingers should be enclosed separately. The axis of the thumb cover shall be turned against the palm so as to allow the tip of the thumb to face the tip of the forefinger.

PROTECTIVE GLOVES shall allow the fingers of the wearer to be closed with ease and the hand to be moved sideways freely from the wrist.

PROTECTIVE GLOVES shall be made so that at least the required minimum LEAD EQUIVALENT is effective without any interruption over their entire surface, front and back, including finger and wrist.

PROTECTIVE GLOVES shall be designed and manufactured so that any cracks and splitting of the protective material used that could reduce its ATTENUATION properties can be identified by visual examination.

Any external covering material shall be detachable in order that the protective material can be examined during routine inspections.

6.3 Materials

The protective material and covering materials used for PROTECTIVE GLOVES shall be flexible.

The protective material of PROTECTIVE GLOVES shall have a LEAD EQUIVALENT of not less than 0,25 mm Pb over their entire area.

The LEAD EQUIVALENT shall be determined as described in IEC 61331-1, by the inverse broad beam geometry method for the SPECIFIED range of RADIATION QUALITIES, 60 kV, 80 kV, 100 kV, 120 kV and 150 kV, according to 5.5 of IEC 61331-1.

6.4 Dimensions

PROTECTIVE GLOVES may be stated to conform to the standard sizes given in Table 2, in which case they shall be substantially of the shape shown in Figure 1 and shall comply with the inside dimensions given in Table 2.