



NSAI
Standards

Irish Standard
I.S. EN 61331-3:2014

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

I.S. EN 61331-3:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

EN 61331-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2014

ICS

Supersedes EN 61331-3:1999

English Version

**Protective devices against diagnostic medical X-radiation - Part
3: Protective clothing, eyewear and protective patient shields
(IEC 61331-3:2014)**

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
(CEI 61331-3:2014)

Strahlenschutz in der medizinischen Röntgendiagnostik -
Teil 3: Schutzkleidung, Augenschutz und Abschirmungen
für Patienten
(IEC 61331-3:2014)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62B/938/FDIS, future edition 2 of IEC 61331-3, prepared by SC 62B, "Diagnostic imaging equipment", of IEC TC 62, "Electrical equipment in medical practice " was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61331-3:2014.

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) 2015-04-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2017-06-11

This document supersedes EN 61331-3:2002.

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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 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1 AMD 1	2012	Medical electrical equipment_ - Part_1: General requirements for basic safety and essential performance; Amendment_1	-	-
IEC 60601-1	2005	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
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	EN 60601-1-3	2008
			+EN 60601-1-3:2008/corrigendum Mar. 2010	2010
+A1	2013		+A1	2013
			+AC	2014
IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation -- Part 1: Determination of attenuation properties of materials	EN 61331-1	2014
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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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**





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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**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 3: Protective clothing, eyewear and protective patient shields

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

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