



**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

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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)

This European Standard was approved by CENELEC on 2014-06-11. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2017-06-11

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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](http://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:<br>General requirements for basic safety and<br>essential performance; Amendment_1                                                                      | -                                               | -           |
| IEC 60601-1        | 2005        | Medical electrical equipment -- Part 1:<br>General requirements for basic safety and<br>essential performance                                                                                   | EN 60601-1                                      | 2006        |
|                    |             |                                                                                                                                                                                                 | +EN 60601-1:<br>2006/corrigendum<br>Mar. 2010   | 2010        |
|                    |             |                                                                                                                                                                                                 | +AC                                             | 2014        |
|                    |             |                                                                                                                                                                                                 | +A11                                            | 2011        |
| IEC 60601-1-3      | 2008        | Medical electrical equipment -- Part 1-3:<br>General requirements for basic safety and<br>essential performance - Collateral Standard:<br>Radiation protection in diagnostic X-ray<br>equipment | EN 60601-1-3                                    | 2008        |
|                    |             |                                                                                                                                                                                                 | +EN 60601-1-3:<br>2008/corrigendum<br>Mar. 2010 | 2010        |
| +A1                | 2013        |                                                                                                                                                                                                 | +A1                                             | 2013        |
|                    |             |                                                                                                                                                                                                 | +AC                                             | 2014        |
| IEC 61331-1        | 2014        | Protective devices against diagnostic<br>medical X-radiation -- Part 1: Determination<br>of attenuation properties of materials                                                                 | EN 61331-1                                      | 2014        |
| IEC/TR 60788       | 2004        | Medical electrical equipment - Glossary of<br>defined terms                                                                                                                                     | -                                               | -           |

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**IEC 61331-3**

Edition 2.0 2014-05

# **INTERNATIONAL STANDARD**

## **NORME INTERNATIONALE**

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**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

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**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

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### **PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –**

#### **Part 3: Protective clothing, eyewear and protective patient shields**

#### **FOREWORD**

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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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