

## SLOVENSKI STANDARD SIST EN 61331-1:2014

01-december-2014

Nadomešča:

SIST EN 61331-1:2002

Sredstva za zaščito pred rentgenskim sevanjem pri medicinski diagnostiki - 1. del: Ugotavljanje slabilnih lastnosti materialov (IEC 61331-1:2014)

Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials

## iTeh STANDARD PREVIEW

(standards.iteh.ai)

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical - Partie 1: Détermination des propriétés d'atténuation des matériaux

https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-

9d6ebab6176a/sist-en-61331-1-2014

Ta slovenski standard je istoveten z: EN 61331-1:2014

ICS:

11.040.50 Radiografska oprema Radiographic equipment 13.280 Varstvo pred sevanjem Radiation protection

SIST EN 61331-1:2014 en

SIST EN 61331-1:2014

# iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 61331-1:2014

https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-9d6ebab6176a/sist-en-61331-1-2014

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM EN 61331-1

October 2014

ICS 11.040.50

Supersedes EN 61331-1:2002

### **English Version**

## Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials (IEC 61331-1:2014)

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical - Partie 1: Détermination des propriétés d'atténuation des matériaux (CEI 61331-1:2014)

Strahlenschutz in der medizinischen Röntgendiagnostik -Teil 1: Bestimmung von Schwächungseigenschaften von Materialien (IEC 61331-1:2014)

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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

### SIST EN 61331-1:2014

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslay, Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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/936/FDIS, future edition 2 of IEC 61331-1, 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 61331-1:2014.

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
 latest date by which the national standards conflicting with the

This document supersedes EN 61331-1:2002.

document have to be withdrawn

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

## **Endorsement notice**

The text of the International Standard/IEC 61331-1:2014 was approved by CENELEC as a European Standard without any modification.

IEC 61331-3

(standards.iteh.ai) NOTE Harmonised as EN 61331-3.

SIST EN 61331-1:2014 https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-9d6ebab6176a/sist-en-61331-1-2014

## 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:

Publication IEC 60601-1	<u>Year</u> 2005	<u>Title</u> Medical electrical equipment Part 1: General requirements for basic safety and essential performance	<u>EN/HD</u> EN 60601-1	<u>Year</u> 2006
			+EN 60601- 1:2006/corrigendum	2010 า
			Mar. 2010	0044
			+AC	2014
			+A11	2011
+A1	2012		+A1	2013
IEC 60601-1-3	2008 1 Te	Medical electrical equipment Part 1-3: General requirements for basic safety and	EN 60601-1-3	2008
		essential performance - Collateral Standard Radiation protection in diagnostic X-ray		
		equipment		
		SIST EN 61331-1:2014	+EN 60601-1-	2010
	https://stan	ndards.iteh.ai/catalog/standards/sist/175c108b-6a93-4f		1
. A 4	0040	9d6ebab6176a/sist-en-61331-1-2014	Mar. 2010	0040
+A1	2013		+A1	2013
			+AC	2014
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

SIST EN 61331-1:2014

# iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 61331-1:2014

https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-9d6ebab6176a/sist-en-61331-1-2014



IEC 61331-1

Edition 2.0 2014-05

## INTERNATIONAL STANDARD

## NORME INTERNATIONALE

Protective devices against diagnostic medical X-radiation Part 1: Determination of attenuation properties of materials

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical/standards.itch.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-Partie 1: Détermination des propriétés d'atténuation des matériaux

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX

T

ICS 11.040.50 ISBN 978-2-8322-1562-3

Warning! Make sure that you obtained this publication from an authorized distributor.

Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

## CONTENTS

FOF	REWORD	)		4	
1	Scope			6	
2	Normati	ve referenc	es	6	
3	Terms and definitions				
4	Methods to determine the ATTENUATION RATIO				
•					
	4.1 General				
	7.2	4.2.1	General description		
		4.2.1	AIR KERMA RATE measurements		
		4.2.3	RADIATION QUALITIES and RADIATION DETECTOR		
		4.2.4	Signal to noise condition		
		4.2.5	ATTENUATION RATIO evaluation		
	4.3	-	M CONDITION		
		4.3.1	General description		
		4.3.2	AIR KERMA RATE measurements		
		4.3.3	RADIATION QUALITIES and RADIATION DETECTOR		
		4.3.5	Signal to noise condition	.12	
	4.4		oad BEAM CONDITION rds.iteh.ai)		
		4.4.1	General description	.12	
		4.4.2	AIR KERMA RAJE measurements	.12	
		4.4.3 https://	RADIATION QUALITIES and RADIATION DETECTOR 6.27.		
		4.4.4	Signal to holise condition-61331-1-2014		
		4.4.5	ATTENUATION RATIO evaluation	. 14	
	4.5	Calculation	n of the ATTENUATION RATIO for photon-emitting radionuclides	.14	
		4.5.1	Equation	. 14	
		4.5.2	Decay data	. 14	
		4.5.3	Mass ATTENUATION and mass energy-absorption coefficients	.14	
		4.5.4	Verification of the mass- ATTENUATION COEFFICIENTS of the test material	. 15	
5	Determination of ATTENUATION properties			.16	
	5.1	ATTENUATIO	ON RATIO	.16	
		5.1.1	Determination	.16	
		5.1.2	Indication	. 16	
	5.2	BUILD-UP F	ACTOR	. 16	
		5.2.1	Determination	.16	
		5.2.2	Indication	.16	
	5.3	ATTENUATI	ON EQUIVALENT	.16	
		5.3.1	Determination	.16	
		5.3.2	Indication	. 17	
	5.4	LEAD EQUIV	'ALENT	. 17	
		5.4.1	Determination	. 17	
		5.4.2	Indication		
	5.5	LEAD EQUIV	ALENT class for a SPECIFIED range of RADIATION QUALITIES	. 17	
		5.5.1	Materials		
		5.5.2	Standard thicknesses	. 17	

		5.5.3	Conditions for assignment to a LEAD EQUIVALENT class	17
		5.5.4	Indication	18
	5.6	Homogen	neity	18
		5.6.1	Determination	18
		5.6.2	Indication	18
6	Stateme	ent of comp	pliance	18
			Tables of ATTENUATION RATIOS, BUILD-UP FACTORS and first HALF-	19
Bibl	iography	,		24
Inde	ex of defi	ned terms	used in this International Standard	25
Fiaı	ure 1 – N	ARROW BEA	AM CONDITION	g
-			I CONDITION	
-			AD BEAM CONDITION	
Tab	le 1 – St	andard RA	ADIATION QUALITIES for X-RAY BEAMS	15
Tab	le 2 – St	andard gar	mma RADIATION QUALITIES according to ISO 4037-1	16
calc	culated fo	r RADIATIO	ON RATIOS $F_{ m N}$ of lead thicknesses from 0,125 mm to 2 mm on QUALITIES of Table 1 according to the formula given in 4.5.4	20
			ACTOR B measured for RADIATION QUALITIES of Table 1 according 5.2.1 for lead thicknesses 0,25 mm, 0,35 mm and 0,50 mm	21
Tab	le A.3 – culated fo	ATTENUATIO	ON RATIOS $F_N$ of lead thicknesses from 0,125 mm to 7 mm ON QUALITIES of Tables 1 and 2 according to the formula given in SISTEN 61331-1:2014	0.4
4.5. ·	4	https	:://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27- VALUE LAYERS.in.mm.Al.of.RADIATION,QUALITIES of Table 1 as a	21
fund	ction of a	dditional le	ead filters of different thicknesses in the range from 0,125 mm	22
Tab	le A.5 –	First HALF-	VALUE LAYERS in mm Cu of RADIATION QUALITIES of Table 1 as a ead filters of different thicknesses in the range from 0,125 mm	
	clion of a . mm	uullional le	sau milers of uniterent unicknesses. In the range from 0,125 mm	23

### – 4 –

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION -

## Part 1: Determination of attenuation properties of materials

## **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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user. (Standards.1121.21)
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter. https://standards.itch.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-
- 5) IEC itself does not provide any attestation of conformity independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61331-1 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 61331-1, published in 1994. It constitutes a technical revision. This second edition has been adapted to apply to the present technology. In particular, this second edition is consistently applicable to lead- and non-lead-containing materials. The essential changes and extensions are:

- extension of the scope to cover photon-emitting radionuclides;
- improved methods to determine the ATTENUATION RATIO;
- addition of the so-called inverse BROAD BEAM CONDITION;
- addition of a method to calculate the ATTENUATION RATIO of photon-emitting radionuclides;
- definition of new standard X- and gamma RADIATION QUALITIES used for testing;
- addition of the so-called LEAD EQUIVALENT class;

- 5 -

 tables of ATTENUATION RATIOS, BUILD-UP FACTORS and first HALF-VALUE LAYERS for the standard RADIATION QUALITIES filtered with different thicknesses of lead.

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

FDIS	Report on voting	
62B/936/FDIS	62B/942/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 of 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.
   https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-

9d6ebab6176a/sist-en-61331-1-2014
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.

IEC 61331-1:2014 © IEC 2014

## PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION -

**-** 6 **-**

## Part 1: Determination of attenuation properties of materials

### 1 Scope

This part of IEC 61331 applies to materials in sheet form used for the manufacturing of PROTECTIVE DEVICES against X-RADIATION of RADIATION QUALITIES generated with X-RAY TUBE VOLTAGES up to 400 kV and gamma radiation emitted by radionuclides with photon energies up to 1,3 MeV.

This Part 1 is not intended to be applied to PROTECTIVE DEVICES when these are to be checked for the presence of their ATTENUATION properties before and after periods of use.

This Part 1 specifies the methods of determining and indicating the ATTENUATION properties of the materials.

The ATTENUATION properties are given in terms of:

- ATTENUATION RATIO, Teh STANDARD PREVIEW
- BUILD-UP FACTOR; (standards.iteh.ai)
- ATTENUATION EQUIVALENT;

together with, as appropriate, an indication of homogeneity and mass per unit area.

https://standards.iteh.ai/catalog/standards/sist/175c108b-6a93-4fc8-bd27-

Ways of stating values of ATTENUATION aproperties in 2 compliance with this part of the International Standard are included.

Excluded from the scope of this International Standard are:

- methods for periodical checks of PROTECTIVE DEVICES, particularly of PROTECTIVE CLOTHING,
- methods of determining ATTENUATION by layers in the RADIATION BEAM, and
- methods of determining ATTENUATION for purposes of protection against IONIZING RADIATION provided by walls and other parts of an installation.

## 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/AMD1:2012

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