BS EN 61331-3:2014

BSI Standards Publication

Protective devices against diagnostic medical X-radiation

Part 3: Protective clothing, eyewear and protective patient shields

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 61331-3:2014. It is identical to IEC 61331-3:2014. It supersedes BS EN 61331-3:1999, which will be withdrawn on 11 June 2017.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2014

ISBN 978 0 580 74635 2
ICS 11.040.50; 13.280; 13.340.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2014.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61331-3

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.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav 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

Ref. No. EN 61331-3:2014 E

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.

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 61331-3:2014 was approved by CENELEC as a European Standard without any modification.

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.

Publication	Year	Title	EN/HD	Year
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	-	-

CONTENTS

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.

Table 2 – Standard sizes of PROTECTIVE GLOVES

Standard size	Letter symbol	Inside dimension cm				
		Length			Half-circumference	
		A	*B*	*C*	*D*	*E*
Small	S	35	11	7	16	11
Medium	M	35	11,5	7	17	12
Large	L	35	12	7	18,5	13
Dimensions A to E are shown in Figure 1; they are minimum dimensions.						

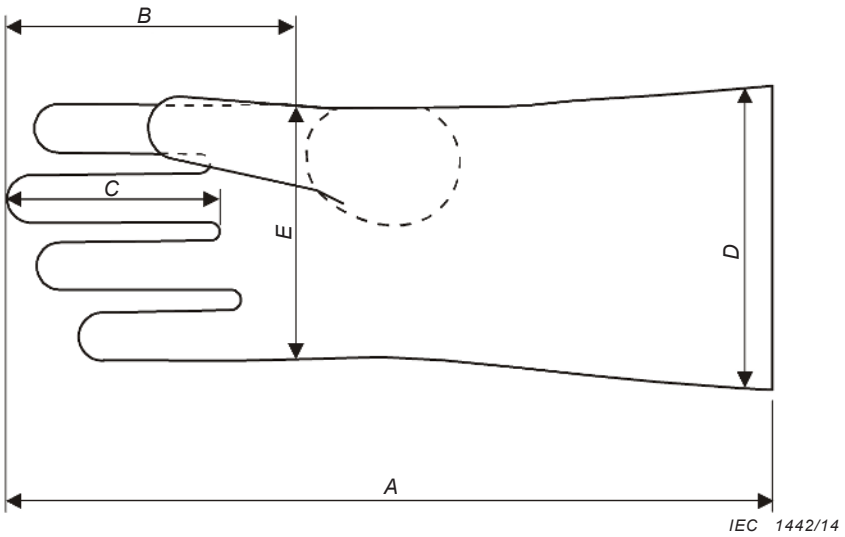

Figure 1 – Inside dimensions of PROTECTIVE GLOVES

6.5 Marking

Each PROTECTIVE GLOVE shall carry the information called for under items a) to e) of Table 3 below.

The information shall be marked clearly and permanently, and shall be attached to the glove itself. The marking should be near the edge of the cuff and shall include the following:

Table 3 – Information and examples for marking PROTECTIVE GLOVES

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 0,25
c) 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 b), by adding an oblique stroke, / , followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV - 150 kV
d) If applicable, letter symbols corresponding to the size according to Table 2.	MS
e) Reference to this standard, given as "IEC 61331-3:2014".	

6.6 Statement of compliance

If compliance of PROTECTIVE GLOVES with this standard is to be stated, it shall be indicated as follows:

Protective glove xyz[1)] Pb 0,25[2)]/60-150[3)] MS[4)] IEC 61331-3:2014[5)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) standard size according to Table 2 (medium);

5) year of publication of this standard.

The standard size according to Table 2 may be omitted in the statement of compliance.

7 PROTECTIVE MITTENS

7.1 General

NOTE PROTECTIVE MITTENS with open palms are intended for special procedures where full perception of touch is essential, for example when handling syringes or during interventional procedures when the possibility cannot be excluded that the hands or forearms of the OPERATOR come into the RADIATION BEAM or into an area of high RADIATION intensity due to STRAY RADIATION.

7.2 Design

PROTECTIVE MITTENS shall cover the entire hand except the palm and the inside of the thumb, and are intended to cover at least half of the forearm.

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

PROTECTIVE MITTENS shall be made so that at least the required minimum LEAD EQUIVALENT is effective without any interruption over their entire surface, except the palm and the inside of the thumb.

PROTECTIVE MITTENS 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.

7.3 Materials

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

The protective material of PROTECTIVE MITTENS 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 kV, according to 5.5 of IEC 61331-1.

7.4 Dimensions

PROTECTIVE MITTENS may be stated to conform to the standard size given in Figure 2. If so, they shall be substantially of the shape shown in Figure 2, and they shall comply with the inside dimensions given in this figure.

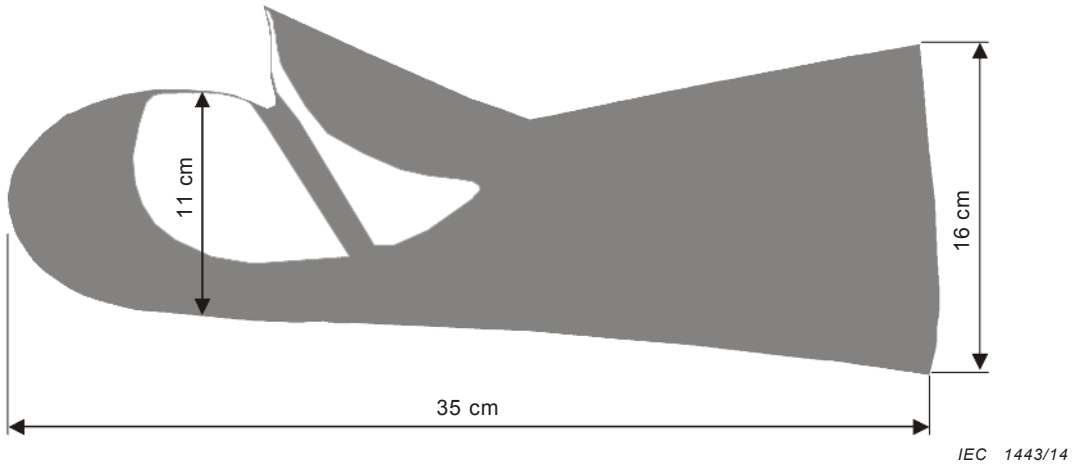

Figure 2 – Inside minimum dimensions of PROTECTIVE MITTENS

7.5 Marking

Each PROTECTIVE MITTEN shall carry the information called for under items a) to e) of Table 4 below.

The information shall be marked clearly and permanently, and shall be attached to the mitten itself. The marking should be near the edge of the cuff and shall include the following:

Table 4 – Information and examples for marking
PROTECTIVE MITTENS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 0,25
c) 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 b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV -150 kV
d) If applicable, the term "Standard size".	Standard size
e) Reference to this standard, given as "IEC 61331-3:2014".	

7.6 Statement of compliance

If compliance of PROTECTIVE MITTENS with this standard is to be stated, it shall be indicated as follows:

Protective mitten xyz[1)] Pb 0,25[2)]/60-150[3)] Standard size[4)] IEC 61331-3:2014[5)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) if applicable;

5) year of publication of this standard.

8 PROTECTIVE GONAD APRONS

8.1 General

NOTE PROTECTIVE GONAD APRONS are intended to protect the gonads of PATIENTS during RADIOLOGICAL examinations of organs other than those in the region of the lower abdomen, in particular during RADIOLOGICAL examination of the thorax.

8.2 Design

PROTECTIVE GONAD APRONS shall be provided with means for attaching them to the PATIENT and for keeping them in position during the RADIOLOGICAL examination.

8.3 Materials

The material of PROTECTIVE GONAD APRONS shall be flexible.

The LEAD EQUIVALENT of PROTECTIVE GONAD APRONS shall be not less than 0,5 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.

8.4 Dimensions

PROTECTIVE GONAD APRONS shall be classified by size in accordance with Table 5 and shall conform to the dimensions shown in Table 5.

Table 5 – Standard sizes of PROTECTIVE GONAD APRONS

Standard size	Letter symbol	Dimensions cm	
		Length	Width
Children 1	C1	20	25
Children 2	C2	30	30
Adults 1	A1	37	40
Adults 2	A2	45	50
The dimensions given are minimum dimensions.			

8.5 Marking

PROTECTIVE GONAD APRONS shall carry the information called for under items a) to e) of Table 6 below.

The information shall be marked clearly and permanently and shall include the following:

Table 6 – Information and examples for marking
PROTECTIVE GONAD APRONS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 0,5
c) 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 b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV - 150 kV
d) Letter symbols corresponding to the size according to Table 5.	A1
e) Reference to this standard, given as "IEC 61331-3:2014".	

8.6 Statement of compliance

If compliance of a PROTECTIVE GONAD APRON with this standard is to be stated, it shall be indicated as follows:

Protective gonad apron xyz[1] Pb 0,5[2]/60-150[3] A1[4] IEC 61331-3:2014[5]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) standard size (adults 1);

5) year of publication of this standard.

9 SCROTUM SHIELDS

9.1 General

SCROTUM SHIELDS contoured to enclose the male gonads are intended to protect the gonads of PATIENTS against unnecessary IRRADIATION by the RADIATION BEAM and against SCATTERED RADIATION when the gonads are close to or within the properly limited RADIATION BEAM for example during RADIOLOGICAL examination of the pelvis.

In addition to the requirements of 4.1 the ACCOMPANYING DOCUMENTS shall contain a recommendation to use disposable plastic bags to enclose the scrotum or scrotum and penis, for hygienic reasons.

9.2 Design

It is essential that the SCROTUM SHIELD fit around the scrotum, or the scrotum and penis, without gaps.

SCROTUM SHIELDS shall be designed so that the PATIENT can easily put the shield into position by himself.

The opening admitting the root of the scrotum, or scrotum and penis, shall be as small as practicable.

SCROTUM SHIELDS shall be provided with the means for keeping them in position during the entire RADIOLOGICAL examination.

The shields shall consist of protective material covered on all outer and inner surfaces with a water-resistant material allowing for easy cleaning and disinfection.

9.3 Materials

The LEAD EQUIVALENT of SCROTUM SHIELDS shall be not less than 1,0 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.

9.4 Dimensions

SCROTUM SHIELDS shall be provided in a set of suitable sizes.

9.5 Marking

SCROTUM SHIELDS shall carry the information called for under items a) to d) of Table 7 below.

The information shall be marked clearly and permanently and shall include the following:

Table 7 – Information and examples for marking
SCROTUM SHIELDS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres	Pb 1,0
c) 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 b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts	60 kV-150 kV
d) Reference to this standard, given as "IEC 61331-3:2014".	

9.6 Statement of compliance

If compliance of a SCROTUM SHIELD with this standard is to be stated, it shall be indicated as follows, for example:

Scrotum shield xyz[1)] Pb 1,0[2)]/60-150[3)] IEC 61331-3:2014[4)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) year of publication of this standard.

10 OVARY SHIELDS

10.1 General

OVARY SHIELDS, which are often also called "ovarian shields", are intended to protect the gonads of female PATIENTS against unnecessary IRRADIATION by the RADIATION BEAM when the ovaries are within the properly limited RADIATION BEAM in the antero-posterior projection, for example during RADIOLOGICAL examination of the pelvis.

10.2 Design

OVARY SHIELDS shall be designed so that they can be applied easily and shall be provided with means for keeping them in position during the entire RADIOLOGICAL examination.

The shields shall consist of protective material covered on all surfaces with a water-resistant material allowing for easy cleaning and disinfection.

10.3 Materials

The LEAD EQUIVALENT of OVARY SHIELDS shall be not less than 1,0 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.

10.4 Dimensions

Except when OVARY SHIELDS are provided with the facility to adjust them to different sizes, they shall be provided in a set of suitable sizes.

10.5 Marking

OVARY SHIELDS shall carry the information called for under items a) to d) of Table 8 below.

The information shall be marked clearly and permanently and shall include the following:

Table 8 – Information and examples for marking
OVARY SHIELDS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 1,0
c) 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 b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV - 150 kV
d) Reference to this standard, given as "IEC 61331-3:2014".	

10.6 Statement of compliance

If compliance of an OVARY SHIELD with this standard is to be stated, it shall be indicated as follows:

Ovary shield xyz[1)] Pb 1,0[2)]/60-150[3)] IEC 61331-3:2014[4)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) year of publication of this standard.

11 SHADOW SHIELDS

11.1 General

SHADOW SHIELDS, suspended over the PATIENT's body, are intended to intercept the RADIATION BEAM in the areas of the gonads, and are to be used when SCROTUM SHIELDS and OVARY SHIELDS cannot be applied.

11.2 Design

SHADOW SHIELDS shall be provided with means to be placed in a position between the RADIATION SOURCE and the PATIENT so that the shielded areas entirely include the regions of the gonads.

SHADOW SHIELDS shall be suitable to be used in connection with LIGHT FIELD-INDICATORS.

11.3 Materials

The LEAD EQUIVALENT of SHADOW SHIELDS shall be not less than 1,0 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.

11.4 Dimensions

Except when SHADOW SHIELDS are provided with the facility to adjust them to different sizes, they shall be provided in a set of suitable sizes.

11.5 Marking

SHADOW SHIELDS shall carry the information called for under items a) to d) of Table 9 below.

The information shall be marked clearly and permanently and shall include the following:

Table 9 – Information and examples for marking
SHADOW SHIELDS

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 1,0
c) 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 b), by adding an oblique strokem, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV - 150 kV
d) Reference to this standard, given as "IEC 61331-3:2014".	

11.6 Statement of compliance

If compliance of a SHADOW SHIELD with this standard is to be stated, it shall be indicated as follows:

Shadow shield xyz[1)] Pb 1,0[2)]/60-150[3)] IEC 61331-3:2014[4)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE range;

4) year of publication of this standard.

12 PROTECTIVE APRONS FOR DENTAL USE

12.1 General

PROTECTIVE APRONS for DENTAL USE are intended to protect the breasts, upper torso and thyroid of PATIENTS against SCATTERED RADIATION during RADIOLOGICAL dental examinations of teeth and the jaw.

12.2 Design

PROTECTIVE APRONS FOR DENTAL USE for PATIENTS 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 below the gonads, the entire breastbone and the shoulders.

They shall be provided with means for attaching them to the PATIENT and for keeping them in position during the RADIOLOGICAL examination.

PROTECTIVE APRONS for dental use for PATIENTS may include an attached THYROID COLLAR.

12.3 Materials

The material of PROTECTIVE APRONS for dental use shall be flexible.

The LEAD EQUIVALENT of PROTECTIVE APRONS FOR DENTAL USE shall be not less than 0,35 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 RADIATION QUALITY code 70 kV.

NOTE PROTECTIVE APRONS FOR DENTAL USE are used for protection against SCATTERED RADIATION and are tested at the 70 kV TUBE VOLTAGE. However such devices and materials are useful in SCATTERED RADIATION from primary x-ray beams with TUBE VOLTAGE of 80 kV because the scattered spectra of this better matches that of a primary beam having TUBE VOLTAGE 10 kV less.

12.4 Dimensions

PROTECTIVE APRONS FOR DENTAL USE shall be classified by size in accordance with Table 10 and shall conform to the dimensions shown in Table 10.

Table 10 – Standard sizes of PROTECTIVE APRONS FOR DENTAL USE

Standard size	Letter symbol	Dimensions cm	
		Length	Width
Children 1	**DC1**	60	45
Children 2	**DC2**	70	45
Adults 1	**DA1**	80	60
Adults 2	**DA2**	90	60
The dimensions given are minimum dimensions.			

12.5 Marking

PROTECTIVE APRONS FOR DENTAL USE for PATIENTS shall carry the information called for under items a) to e) of Table 11 below.

The information shall be marked clearly and permanently and shall include the following:

Table 11 – Information and examples for marking
PROTECTIVE APRONS FOR DENTAL USE

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres.	Pb 0,35
c) 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 b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	70 kV
d) Letter symbols corresponding to the size according to Table 10.	A1
e) Reference to this standard, given as "IEC 61331-3:2014".	

12.6 Statement of compliance

If compliance of a PROTECTIVE APRON FOR DENTAL USE for PATIENTS with this standard is to be stated, it shall be indicated as follows:

Protective dental apron xyz[1)] Pb 0,35[2)]/70[3)] IEC 61331-3:2014[4)]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT;

3) X-RAY TUBE VOLTAGE;

4) year of publication of this standard.

13 PROTECTIVE EYEWEAR

13.1 General

PROTECTIVE EYEWEAR is 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 eyes of the OPERATOR. To protect the complete body, additional protective devices are recommended to be used, for example, PROTECTIVE APRONS and helmets.

For the purposes of this standard, two different categories of PROTECTIVE EYEWEAR are defined:

– light-duty protective masks;
– heavy-duty protective eye-glasses or goggles.

NOTE Light-duty protective masks are 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, fixed for example on the X-RAY EQUIPMENT, or by fenestrated patient drapes.

13.2 Design

PROTECTIVE EYEWEAR shall consist of a single layer of transparent protective material and shall be designed to at least completely cover the area of the eyes and shall be affixed in or to a

frame with means to attach to the head or ears. Such eye coverage may be supplemented by designs using a curved lens and frame, or by separate side-shields.

13.3 Materials

The protective material shall be rigid to prevent optical distortion.

a) Light-duty protective masks shall be made of transparent lead acrylic plastic material and shall have an ATTENUATION RATIO of at least 2 over their entire area.

b) Heavy-duty protective eyeglasses or goggles shall be made of transparent leaded glass and shall have a LEAD EQUIVALENT of not less than 0,50 mm Pb over their entire area, including any side-shields.

The ATTENUATION RATIO shall be determined as described in IEC 61331-1, by the NARROW BEAM geometry method and shall meet or exceed the above values for RADIATION QUALITY 120 kV.

The LEAD EQUIVALENT shall be determined as described in IEC 61331-1, by the NARROW BEAM geometry method and shall meet or exceed the above value for RADIATION QUALITY 150 kV.

13.4 Marking

PROTECTIVE EYEWEAR shall carry the information called for under items a) to d) of Table 12 below, at least in the ACCOMPANYING DOCUMENTS.

The information shall be marked clearly and permanently and shall include the following:

Table 12 – Information and examples for marking
PROTECTIVE EYEWEAR

Information	Example
a) Name or trade mark of MANUFACTURER or supplier.	xyz
b) Value of the LEAD EQUIVALENT in thickness of lead, expressed as the symbol Pb followed by the thickness in millimetres OR value of the ATTENUATION RATIO, expressed as the symbol F_N.	Pb 0,50 F_N 2,0
c) X-RAY TUBE VOLTAGE range used for the determination of the values of the LEAD EQUIVALENT OR ATTENUATION RATIO, appended to the marking given in accordance with item b), by adding an oblique stroke, /, followed by the value of the X-RAY TUBE VOLTAGE range in kilovolts.	60 kV - 150 kV F_N 2,0/120 kV
d) Reference to this standard, given as "IEC 61331-3:2014".	

13.5 Statement of compliance

If compliance of PROTECTIVE EYEWEAR with this standard is to be stated, it shall be indicated as follows:

X-ray protective eyeglasses (or goggles) xyz[1] Pb 0,50[2]/150[3] IEC 61331-3:2014[4]

X-ray protective mask xyz[1] F_N 2[2]/120[3] IEC 61331-3:2014[4]

1) name or trade mark of MANUFACTURER or supplier;

2) LEAD EQUIVALENT (eyeglasses or goggles); or ATTENUATION RATIO (masks);

3) X-RAY TUBE VOLTAGE;

4) year of publication of this standard.

Bibliography

ISO 3635:1981, *Size designation of clothes – Definitions and body measurement procedure*

EN 420:2003, *Protective gloves – General requirements and test methods*
Amendment 1:2009

Index of defined terms used in this standard

NOTE In the present document terms defined either in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC/TR 60788:2004 or in this International Standard have been used. These defined terms can be looked up at the IEC website http://std.iec.ch/glossary.

X-RAY EQUIPMENT ..... IEC 60601-1-3:2008, 3.78
X-RAY TUBE VOLTAGE ..... IEC 60601-1-3:2008, 3.88

_____

This page deliberately left blank

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™