उत्पाद मैन्युअल
आई एस/आईईसी 61331-3 : 2014 के अनुसार
नैदानिक चिकित्सा एक्स-विकिरण से सुरक्षा के लिए उपकरण
भाग 3 सुरक्षात्मक रोगी ढालें के लिए

दस्तावेज़ संख्या – पीएम/आईएस/आईईसी 61331-3/1/मार्च 2022

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION
PART 3 PROTECTIVE CLOTHINGS, EYEWEAR AND PROTECTIVE PATIENT SHIELDS
ACCORDING TO IS/ IEC 61331-3 : 2014

Document No - PM/IS/IEC 61331-3/1/March 2022

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

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PRODUCT MANUAL
FOR
PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X –RADIATION
ACCORDING TO IS/IEC 61331-3 : 2014

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1.	**Product**	:	IS/ IEC 61331-3 : 2014
	Title	:	Protective Devices Against Diagnostic Medical X-Radiation Part 3 Protective Clothing, Eyewear and Protective Patient Shields
	No. of Amendments	:	0
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Clause 5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3 of IS/ IEC 61331- 3 :2014
b)	**Grouping guidelines**	:	Please refer ANNEX – A
c)	**Sample Size**	:	Two Finished Product
		:	
3.	**List of Test Equipment**	:	Please refer ANNEX – B
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX – C
5.	**Possible tests in a day :**		
	All Tests.		

6.	**Scope of the Licence :**	
	"Licence is granted to use Standard Mark as per IS/ IEC 61331-3 : 2014 for the product 'Protective Devices Against Diagnostic Medical X-Radiation Part 3 Protective Clothing, Eyewear and Protective Patient Shields'for use in X-RADIATION up to …. kV."	
	Name of the product	Protective Apron with Thyroid Collars/ Protective Apron without Thyroid Collars/ Thyroid Collars/ Protective Gloves/ Protective Mittens/ Protective Gonad Aprons/ Scrotum Shields/ Ovary Shields/ Shadow Shields/ Protective Apron for Dental Use with thyroid collar/ Protective Apron for Dental Use without thyroid collar/ Protective Eyewear
	Category/ Variety/ Size	As applicable from ANNEX A

ANNEX A

1. Following guidelines shall be followed for grant of licence and change in scope of licence:

Sl. No.	Clause	Product Name	Varieties/Sizes	Grouping Guideline
1	5	**Protective Apron**	Light Duty Light Duty Closed Heavy Duty Heavy Duty Closed	Provided the raw material is same, sample of 'Heavy Duty'/ Heavy Duty Closed' protective apron to be tested for considering GoL /Inclusion of all variety/ size. Sample of 'Light Duty'/ 'Light Duty Closed' to be tested for considering GoL/Inclusion of 'Light Duty' and Light Duty Closed' apron.
2	5	**Thyroid Collars**	Not Defined/ Suitable Sizes	Sample of any variety/ size of product to be tested for considering GoL /Inclusion.
3	6	**Protective Gloves**	Small Medium Large	Sample of any variety /size of the product to be tested for requirement of 'material', sample of each variety/ size to be tested separately for other requirements for considering GoL /Inclusion.
4	7	**Protective Mittens**	Standard Size	Sample of any variety/ size of product to be tested for considering GoL /Inclusion.
5	8	**Protective Gonad Aprons**	Children 1 Children 2 Adults 1 Adults 2	Sample of any variety /size of the product to be tested for requirement of 'material', sample of each variety/ size to be tested separately for other requirements for considering GoL /Inclusion.
6	9	**Scrotum Shields**	Not Defined/ Suitable Sizes	Sample of any variety/ size of product to be tested for considering GoL /Inclusion.
7	10	**Ovary Shields**	Not Defined/ Suitable Sizes	Sample of any variety/ size of product to be tested for considering GoL /Inclusion.
8	11	**Shadow Shields**	Not Defined/ Suitable Sizes	Sample of any variety/ size of product to be tested for considering GoL /Inclusion.

9	12	**Protective Apron for Dental Use**	Children 1	Sample of any variety /size of the product to be tested for requirement of 'material', sample of each variety/ size to be tested separately for other requirements for considering GoL /Inclusion.
			Children 2	
			Adults 1	
			Adults 2	
10	13	**Protective Eyewear**	Light-duty protective masks	Sample of any variety /size of the product to be tested for requirement of 'material', sample of each variety/ size to be tested separately for other requirements for considering GoL /Inclusion.
			Heavy-duty protective eye-glasses or googles	

2. Manufacturers shall submit declaration for each variety of the product intended to be covered in scope indicating Product name, variety, size, material, design no./ model no.(etc.). Any change in the declared parameters to be informed to BIS. The scope of the licence may be restricted based on the manufacturing and testing capability of the manufacturer.

3. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation, to the extent possible.

ANNEX B

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Design – Clause 5.2, 6.2, 7.2, 8.2, 9.2, 10.2, 11.2, 12.2, 13.2	Measuring Tape, Measuring Scale
2	Dimension- Clause 5.4, 6.4, 7.4, 8.4, 9.4, 10.4, 11.4, 12.4, 13.4	Vernier Calliper, Measuring Tape
3	Material – Clause 5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3	X-Ray Machine (Radiography System) *
4	Material – Clause 5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3	Ray Safe XI Base Unit *
5	Material – Clause 5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3	Ray Safe XI R/F Detector *
6	Material – Clause 5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3	Ray Safe XI Survey Detector *

* - Exempted, if the test for material is subcontracted or Raw material with test certificate is used for manufacturing the product.

The above list is indicative only and may not be treated as exhaustive.

ANNEX C

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirement of IS/ IEC 61331-3 : 2014

5. CONTROL UNIT – Single Type of protective devices manufactured in a day from the same raw material consignment shall constitute one control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. HYGIENIC CONDITIONS – Wherever applicable**,** hygienic conditions shall be complied in day to day production and quality control activities. Schedule for each activity for this purpose shall be displayed prominently in the factory premises and records of compliance shall be maintained.

7. REJECTIONS – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
5.1, 5.2, 5.3, 5.5.1, 5.5.2, 5.5.3	General Requirements	**5.1, 5.2, 5.3, 5.5.1, 5.5.2, 5.5.3**	**IS/IEC 61331-3**	**R**	Each Piece		
5.5.1, 5.5.2, 5.2, 6.2, 7.2, 8.2, 9.2, 10.2, 11.2, 12.2, 13.2	Design	**5.5.1, 5.5.2, 5.2, 6.2, 7.2, 8.2, 9.2, 10.2, 11.2, 12.2, 13.2**	**IS/IEC 61331-3**	**R**	Three	Each control Unit	-
5.3, 6.3, 7.3, 8.3, 9.3, 10.3, 11.3, 12.3, 13.3	Protective Material	**5.5**	**IS/IEC 61331-1**	**S**	One	Each consignment received	No further testing is required if accompanied with the Test Certificate or with BIS Standard Mark
5.5, 6.5, 7.5, 8.5, 9.5, 10.5, 11.5, 12.5	Dimensions	**5.5, 6.5, 7.5, 8.5, 9.5, 10.5, 11.5, 12.5**	**IS/IEC 61331-3**	**R**	One	Each control Unit	-
5.5, 6.5, 7.5, 8.5, 9.5, 10.5, 11.5, 12.5, 13.5	Marking	**5.5, 6.5, 7.5, 8.5, 9.5, 10.5, 11.5, 12.5, 13.5**	**IS/IEC 61331-3**	**R**	Each Piece		-

In case of any failure twice the number of samples shall be drawn and tested and control shall be accepted if retested sample pass.

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.