

केन्द्रीय मोहर विभाग 3

हमारा संदर्भ- केन्द्रीय मोहर विभाग-3/16: आई एस-7620 (पार्ट 1)/13450

27 जुलाई 2016

विषय- एक्स-रे उपकरण के पुनरीछिन मानको का अनुपालन

एक्स-रे उपकरण के भारतीय मानक पुनरीछिन कर दिए गये हैं। अनुपालन के लिए विवरण संलग्न हैं।

इसे सख्तम प्राधिकारी के अनुमोदन से जारी किया गया है।

सभी संबंधित पक्षकारों से अनुरोध है कि अनुपालन सुनिश्चित करें।

एचटर्जी

वैज्ञानिक ई (सी एम डी-3)

प्रमुख (सी एम डी-3)

सभी क्षेत्रीय/शाखा कार्यालय/ भारतीय मानक ब्यूरो प्रयोगशाला/ एम.एच.डी
आई टी एस विभाग-बीआईएस इंटरनेट एवं बीआईएस वेबसाइट पर डालने हेतु

CENTRAL MARKS DEPARTMENT-3

Our Ref: CMD-3/16: IS 7620 (Pt 1)/13450

27.7.2016

Subject: Implementation of Revised Standards for X-Ray Equipment.

The Indian Standards for X-Ray Equipment have been revised. Details regarding implementation of the revised specification are enclosed.

It is issued with the approval of competent authority

All concerned are requested to ensure compliance.

**A.Chatterjee
Sc. E (CMD-3)**

Head CMD-3

Circulated to all RO/Bo/SBOs /Labs/MHD

Copy to : ITS for hosting on Intranet and BIS website

CENTRAL MARKS DEPARTMENT-3

Our ref: CMD-3/16:7620 (Part 1)

26.07.2016

Subject : Indian Standards on Medical diagnostic X-ray machine(s)

Kind attention is invited to the following 4 Indian Standards on Diagnostic medical X-ray equipment :

1. IS 7620(Pt 1) : 1986 - Diagnostic Medical X Ray equipment: Gen and safety requirements
2. IS 7620 (Pt 2): 1986 - Diagnostic Medical X Ray equipment: Performance requirements
3. IS 7620(Pt 3): 1991 - Diagnostic Medical X Ray equipment: Radiation safety requirements
4. IS 13709: 1993 - Dental X Ray equipment – Radiation safety

The above ISS have now been revised and replaced by adopting the corresponding IEC Standards .
Details as given below :

1. IS 13450(Part 2/Sec 43):2016/IEC 60601-2-43 : 2010 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 43 X-ray equipment for interventional procedures (First Revision)
2. IS 13450(Part 2/Sec 44):2016/IEC 60601-2-44 : 2009 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 44 X-ray equipment for computed tomography (First Revision)
3. IS 13450(Part 2/Sec 45):2016/IEC 60601-2-45 : 2011 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 45 Mammographic X-ray equipment and mammographic stereotactic devices (First Revision)
4. IS 13450(Part 2/Sec 54):2016/IEC 60601-2-54 : 2009 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 54 X-ray equipment for radiography and radioscopy
5. IS 13450(Part 2/Sec 63):2016/IEC 60601-2-63 : 2012 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 63 Dental extra-oral X-ray equipment
6. IS 13450(Part 2/Sec 65):2016/IEC 60601-2-65 : 2012 - Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 65 Dental intra-oral X-ray equipment

In addition the following standards shall also be used in conjunction with above :

7. IS 13450(Part 1):2008/IEC 60601-1 - Medical Electrical Equipment - Part 1 : General Requirements for Basic Safety And Essential Performance
8. IS 13450(Part 1/Sec 3):2014/IEC60601-3 : 2008 - Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 3 Collateral Standards : Radiation Protection in Diagnostic X-ray Equipment

It may please be noted that the scope of above new standards [IS 13450 (Part 2/Sec 43, 44, 45, 54, 63 & 65) : 2016] covers **Safety** (Electrical, Mechanical & General) **as well as Performance requirements** whereas the existing licences, under BIS Certification Scheme, are being operated for Safety (Electrical & Mechanical) parameters only as per IS 7620 (Part 1) : 1986.

Therefore, for switch over from existing IS 7620 (Part 1) : 1986 to IS 13450 (Part 2/Sec 43, 44, 45, 54, 63 & 65) : 2016 , the manufacturers of X-ray machines would be required to ensure the conformity of their product for all the parameters including the performance parameters.

With the issuance of the revised Standards, the manufacturers are required to be equipped with complete testing facilities as per the applicable standards. In this case it may please be noted that BIS will be considering certification for electrical, mechanical , general safety and performance requirements only. Radiation safety requirements shall be verified by Atomic Energy Regulatory Board (AERB).

Since the manufacturers have to create additional test facilities for the safety and performance requirements, both the old and new ISSs shall be running concurrently till 27 May 2017.

In view of the above, the BOs operating licenses for the above product are requested to ensure the following:

1. Intimate the licensees regarding revision of the existing and implementation of the new standards.
2. The present standard (IS 7620 Pt 1) covers mechanical and safety requirements of all types of X Ray equipment. However different types of X Ray equipment have been categorized and placed under separate standards after the revision. As such, BOs may kindly examine the varieties covered in the present scope of the licences and how the same is to be covered in the revised standard(s).
3. The licensees to be advised to equip themselves with the requisite testing facilities as per the revised standard(s) under which the present scope of their licence will be covered. In case of any difficulty, the same needs to be brought to the notice of CMD-3.

Confirmation regarding the actions taken and feedback on the same shall be sent to CMD-3 by the BOs latest by 12 Aug 2016.

Switchover guidelines, STI , MF are being prepared and shall be finalized based on the feedback received from the BOs.

Sd/-
A.Chatterjee
Sc-E, CMD-3

Head (CMD-3) – Sd/-