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SYNOPSIS

Doc: MHD 15 (11498) IS 13450 (Part2/Sec68):2019/ IEC 60601-2-68:2014
Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 68 X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

a) Scope:

This Indian Standard applies to the Basic Safety and Essential Performance of X-ray based image-guided Radiotherapy equipment for use with External Beam Equipment (EBE).

This particular standard covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with EBE for the purpose of IGRT. It covers aspects of communication and relationships between the External Beam Equipment and X-ray imaging devices, attached or not directly attached to, but in the same radiation shielded area as, and dedicated for use only with, the external Beam Equipment.

b) Salient features of content:

This particular standard deals with equipment for Real Time X-IGRT, Online X-IGRT and Offline X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT External Beam System (X-IGRT EBS). For example the manufacturer will provide an interactive interface for user interaction with the correction suggested by the system.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE Systems the content of that clause or subclause will say so. If that is not the case, the clause or subclause applies only to X-IGRT Equipment.

This particular standard, with the inclusion of Type Tests and Site Tests, applies respectively to the manufacturer and some installation aspects of X-IGRT EBE Systems intended to be for:-

- a) normal use, operated under the authority of appropriately licensed or Qualified Person Operators by having the required skills for a particular medical application, for particular specified clinical purposes, e.g. Stationary Radiotherapy or Moving Beam Radiotherapy
- b) maintained in accordance with the recommendations given in the Instructions for Use.
- c) subject to regular quality assurance performance and calibration checks by a Qualified Person.

In this particular standard, all references to installation refer to installation in the Responsible Organisation's premises.

c) Type/grades/classes, if any covered in the standard: Nil.

d) Disclaimer (to be automatically provided by the program/ software)

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