

IEC STANDARDS AND DIGITAL RADIOLOGICAL EQUIPMENT

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The International Electrotechnical Commission (IEC) is a global standards organization established under the Presidency of Lord Kelvin in 1906. All medical equipment standards in IEC are dealt with by Technical Committee (TC) 62, and within this Medical Imaging Equipment Standards are developed under the umbrella of Subcommittee (SC) 62B. In September 2005 a special meeting of a Steering Group of IEC SC 62B was held to review x-ray standards and to identify an approach to the development of new standards in this field. This was followed by practical developments and further refinements in planning at the meeting of SC 62B in Delft in Oct 2006. At this meeting the agenda for new standards was definitively established and consolidated, concentrating on whole systems, with the aspiration of returning later to acceptance test and QA standards once system standards are established over the radiological range. These include a standard for Exposure Index for Digital Systems. A liaison between SC 62B and SENTINEL was also established. In addition it was decided to review SC 62 B's liaison's with the IAEA and ICRP and some national/international professional bodies.

The initial liaison meeting between IEC 62B AND SENTINEL concentrated on criteria for acceptance testing; constancy testing and performance of equipment ranging from simple dental systems to the most complex of interventional systems. This was motivated in part by different requirements and approaches in the EU Medical Exposure and Medical Device Directives. Of particular concern were approaches to acceptance testing and commissioning, given the immanent revision of RP 91 on criteria for the acceptability of equipment. It is hoped that this initiative will help reduce potential and actual misunderstandings that can and do occur in this area and lead to the development of common ground between the industry and end users. This paper will review the new IEC standards and liaisons agenda.

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