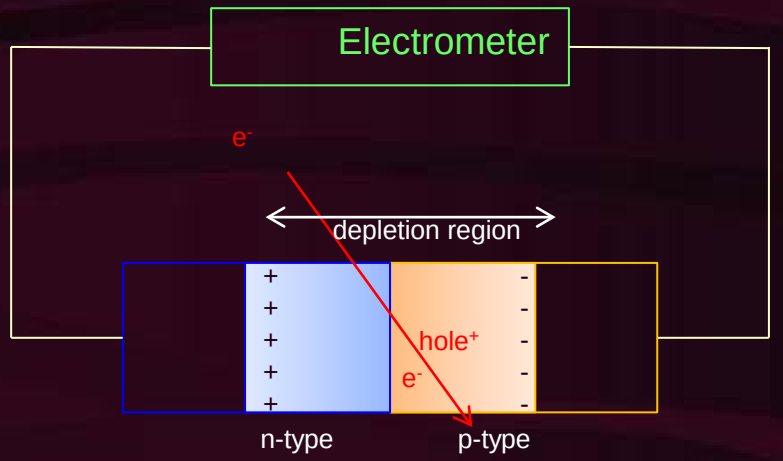

Relevant IEC Standards

May 28, 2024

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X-ray imaging dosimetry challenges
CCRI Webinar Series

IEC International Electrotechnical Commission

CCRI

Disclosures

- No conflicts of interest
- Products named or shown in this presentation are not endorsed

The IEC

- The International Electrotechnical Commission (IEC) is a 118-year old organization that designs, coordinates, and publishes international standards for electronics and telecommunications
- Membership includes the electrotechnical standards organizations from over 170 participating countries.
  - For example, ANSI represents the U.S.
- Standards are documents (not radiation standards)
- The IEC publishes around 10,000 IEC International Standards

- Main difference is their scope
- ISO has a more broad scope
- Some overlap

The Importance of IEC Standards

- Provides the framework that allows governments and regulatory bodies to build companies of all sizes to buy and sell safe and reliable products
- IEC standards serve as the basis for risk and quality management
- Used in testing and certification to verify that manufacturer promises are kept

- Clinical medical physicists' perspective (imaging and radiation therapy)
  - Need to trust the equipment they are purchasing
  - Don't have time to test everything
  - Reduces confusion when manufacturers aren't using the same terminology
- Standards laboratories' perspective (x-ray imaging)
  - Provides standard x-ray beam qualities
  - Sets guidelines for test conditions

Have you ever seen this written on your detector brochure? "Reference class in accordance with IEC 60731"

IEC Committees for X-ray Imaging

SC 62B Medical imaging equipment, software, and systems

https://www.medicaldevice-network.com/news/ge-healthcare-x-ray-system-radiologists/

Set requirements for air-kerma reproducibility, linearity, tube voltage accuracy, ripple, tube current, etc.

SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry

SC 62C Subcommittee(s) and/or Working Group(s)

Label	Title
Working Group	
WG 1	Radiotherapy systems for planning, delivery, and information management
WG 2	Nuclear medicine instrumentation
WG 3	Performance of dosimeters
Joint Working Groups	
JWG 5	Radionuclide calibrators linked to TC 45, ISO/TC 85/SC 2

WG3

2024 in-person meeting attendees

- 35 individual members from 14 countries
- Members represent manufacturers, PSDLs, SSDLs, clinical physicists, regulatory bodies, researchers
- Actively maintaining six standards
- Meet in person once per year
- Various project groups meet regularly
- Convenor (aka chair) – Wesley Culberson

Relevant Standards Maintained by 62C WG3

Current Edition	Title	Stability Date
IEC 60580 Ed 3.0 2019-11-12	Medical electrical equipment - Dose area product meters	2025
IEC 61267 Ed 2.0 2005-11-09	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	2023
IEC 61674:2012 Ed 2.0 2012-11-29	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	2023
IEC 61676:2023 Ed 2.0 2023-03-21	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	2026

IEC 61267 Ed 2.0

Title: *Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics*

- Standard beams such as RQR, RQA, RQC, RQT, etc. are defined
- 3rd edition project leader: Stefan Potjinger – PTB - Germany
  - must be finalized before August 2025!

From the introduction

"However, since the publication of the second edition in 2005 many additional X-RAY RADIATION CONDITIONS have emerged. Due to the large number of this X-RAY RADIATION CONDITIONS, it is impractical to list their nominal first aluminium half-value-layers. This third edition of this standard introduces a systematic procedure for the characterization and description of X-RAY RADIATION CONDITIONS for these additional X-RAY RADIATION CONDITIONS, as well as a method for the validation of the associated half-value-layers."

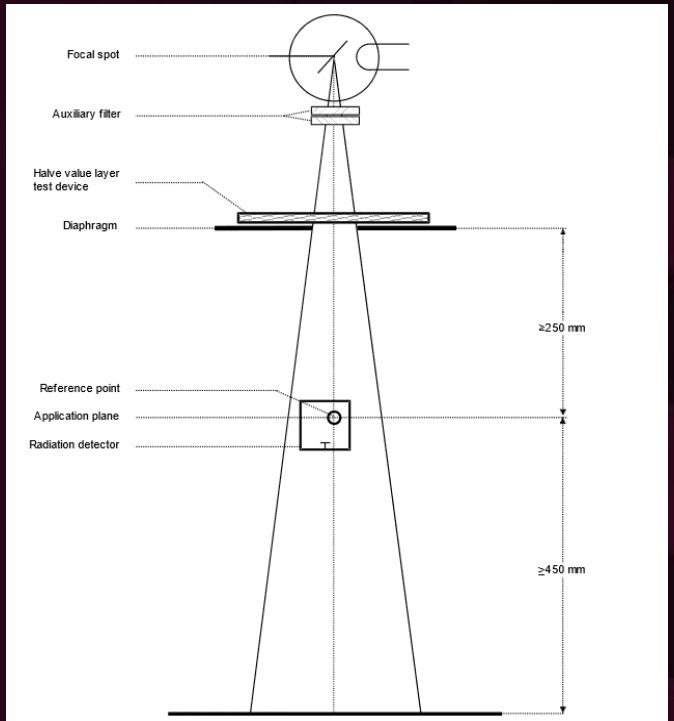

Figure 1 – Measuring arrangement for achieving standard X-RAY RADIATION CONDITIONS RQR 2 to RQR 10

IEC 61674:2012 Ed 2.0

- Title: *Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging*
- Specifies the performance and related constructional requirements of diagnostic dosimeters – air kerma based
- Radiography including mammography and CT (<150 kV)
- X-ray multimeters (XMMs)
- 3rd edition project leader: Stefan Potjinger – PTB - Germany
- In final stages for Ed 3.0
  - Updated for new beam qualities
  - Removed analog displays, non-rechargeable batters
  - Removed redundant tests

IEC 61676:2023 Ed 2.0

- Title: *Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*
- Stability date 2026
- Fairly short and narrow standard
- Considering whether practical peak voltage (PPV) is too narrow of a definition?
- Data from TraMeXI will guide the update of this standard

Looking Forward

- Data from TraMeXI project will inform changes to IEC Standards
  - Update the range of relevant radiation qualities
  - Consider recommendations on reference radiation qualities for IEC 61267
  - Distinguish between reference class and field-class detectors for diagnostic imaging dosimetry for IEC 61674
  - Consider a more open-concept beam-quality spectrum catalogue
  - Establish better performance characteristics of XMMs (uncertainty budgets) for IEC 61676

Parting Comments

- IEC Standards are VERY important
- WG3 is actively updated standards as data becomes available
- Timeline for standards development is relatively slow (~5 years), so be patient
- Interested in being involved?
  - Contact your National Committee (NC). The NC is responsible for nominating experts to participate in the development of IEC work
  - Guests are welcome at the WG3 and project level, so you can contact the convenor (me)
  - If face to face meetings represent a hurdle, you may want to influence IEC work from the national level
- Public commenting periods are important. Your chance to give feedback!