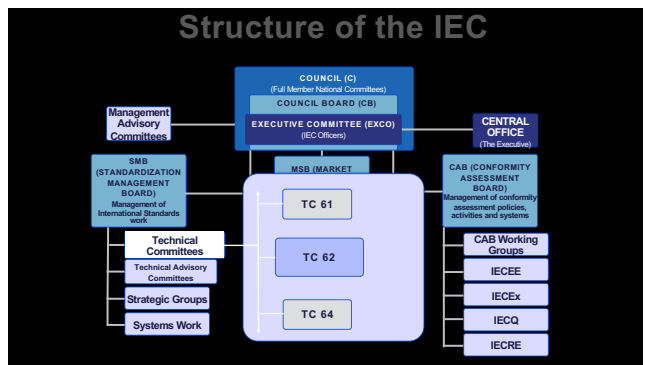
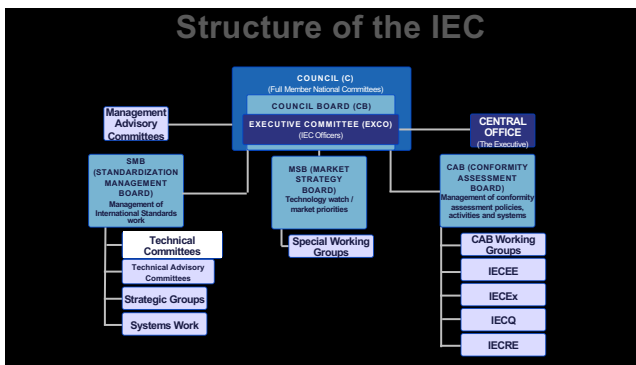
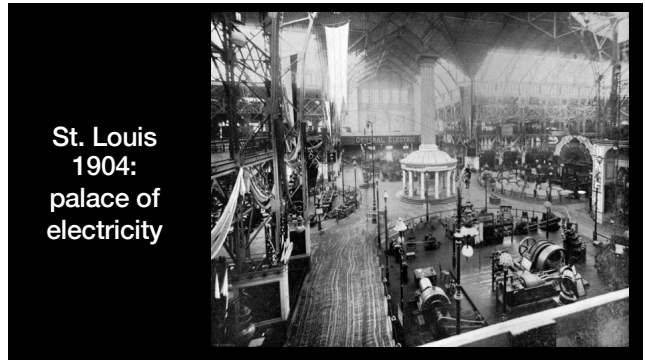


Updates to IEC 62C Standards: Equipment for Radiotherapy, Nuclear Medicine and Dosimetry

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Former Chair, Subcommittee 62C
Convener, WG-1
Chair, US TAG for IEC 62C
Technical Advisor to US National Committee



INTERNATIONAL
ELECTROTECHNICAL
COMMISSION



IEC publications

- International Standard (IS)
- Technical Specification (TS)
- Publicly Available Specification (PAS)
- Technical Report (TR)




What is an IEC International Standard?

- technical guidelines or characteristics developed by experts representing all stakeholders
- based on international consensus
- always voluntary



Consensus

All views of all concerned parties have been taken into account.

Sustained opposition on substantial issues has been overcome.

consensus \neq unanimity

How IEC IS are developed

- Established standards development process
- National Committees involved at each stage
- Technical Committees established for specific fields of activity

Standards development stages

- New Proposal
- Committee Draft
- Committee Draft for vote
- Final Draft International Standard
- International Standard

CENELEC Dresden agreement: ~ 80+% aligned standards

- In Europe:
 - ◆ IEC standards selected for “parallel voting” by CENELEC
 - ◆ When approved, assigned “EN” number
 - ◆ Standards adopted as written and carry the force of law
 - ◆ However, up to EC members to enforce

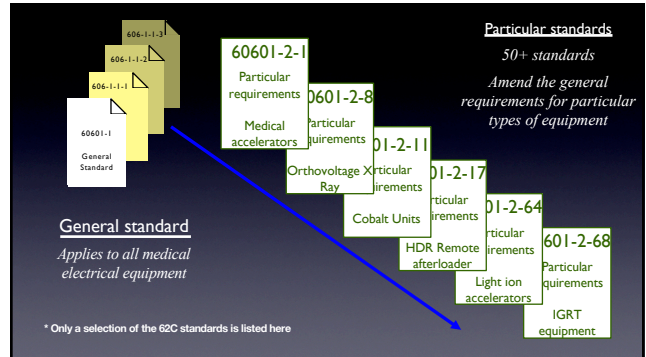
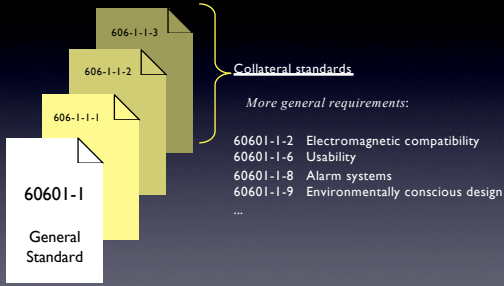
Adoption of IEC Standards

- In US:
 - IEC standards (or sections) incorporated into ANSI standards, FDA regulations, NEMA guidelines, etc.
 - IEC standards can be used as written; FDA requires vendor to report compliance

Input from National Committees

- Through Technical Advisory Group (TAG)
- One TAG for SC 62 B, another for SC 62 C
- TAG recommends to US NC (housed at ANSI)
- USNC submits our votes and comments
- All NC votes and comments discussed by WG

IEC 60601 series of Safety Standards



Safety standards
Requirements for equipment that does not meet definition of "medical electrical equipment"

60580 Dose-area product meters (3 rd Ed 1/2020)	60731 Ion-chamber dosimeters for radiotherapy (Ed 3.1 2016)
61217 Coordinates, Movements and Scales (NWIP)	62083 Safety of TPS systems (3 rd Ed 2022)
62274 Safety of RT Verification Systems (NWIP)	

* Only a selection of the 62C standards is listed here

Technical Reports and Performance standards
Recommendations for performance (other than "essential performance") of medical electrical equipment

60976 Performance characteristics for linear accelerators (future rev)	61948 Routine testing of NM equipment (2 nd Ed 10-2019)
62926 Guidelines for adaptive RT systems (1 st Ed 2019)	61303 Performance of Radionuclide Calibrators (1994)
63183 Error and Warning Messages (1 st Ed 12-2019)	

* Only a selection of the 62C standards is listed here

A Sample of Safety Standards from from SC 62B

	IEC 60601-2-28:2017 RLV Edition 3.0 (2017-06-16) Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	EN
	IEC 60601-2-33:2019+AMD1:2013+AMD2:2015 CSV Edition 3.2 (2019-06-18) Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	EN-FR
	IEC 60601-2-37:2007+AMD1:2015 CSV Edition 2.1 (2015-06-09) Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	EN-FR
	IEC 60601-2-44:2009+AMD1:2012+AMD2:2016 CSV Edition 3.2 (2016-03-31) Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	EN-FR

Clause in CT safety standard regarding Treatment Planning

201.101 Requirements for CT SCANNERS providing images for RADIOTHERAPY TREATMENT PLANNING (RTP)

201.101.1 General

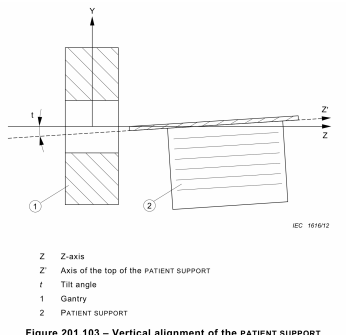
Clause 201.101 applies only to CT SCANNERS whose INTENDED USE includes providing image data for RADIOTHERAPY TREATMENT PLANNING (RTP).

Requirements related to the CT SCANNER (gantry, PATIENT SUPPORT, light markers) and conversion of Hounsfield Units to electron and mass density are addressed.

201.101.2.2 Alignment of the PATIENT SUPPORT in the vertical plane (tilt)

The alignment procedure shall require the accuracy of the alignment to be $\pm 0,5^\circ$ or less with respect to the horizontal plane (Figure 201.103).

Illustration of measurement of tilt of patient support



60601-2-1: Linac Safety Standard

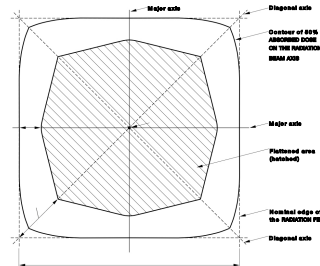
- One of the oldest safety standards from TC 62
- Defines important safety aspects of medical linacs, including requirements for:
 - Dual dosimetry systems
 - Beam off in case of excess dose, asymmetric beam, wrong dose rate
 - etc.



60601-2-1: Linac Safety Standard

- US led development of 4th edition
- Final draft to be distributed for NC vote this fall
- Important changes reflecting modern design:
 - Connectivity
 - Non-isocentric equipment, 6 DoF movements, FFF beams
 - Improved procedures by manufacturers for TYPE TESTS, can delete unnecessarily complex SITE TESTS

60601-2-1: Linac Safety Standard



$$\bar{D}_{area} = \frac{1}{area} \int_{area} D(x, y) dx dy$$

Example clause from Linac Safety standard

201.10.1.2.101.1.6 TERMINATION OF IRRADIATION by monitoring device

- a) Both DOSE MONITORING SYSTEMS shall be capable, independently, of TERMINATING IRRADIATION. Means shall be provided to test the correct operation of both systems.
- b) Both systems in a REDUNDANT DOSE MONITORING COMBINATION shall be set to TERMINATE IRRADIATION when the selected number of DOSE MONITOR UNITS has been reached.
- The PRIMARY DOSE MONITORING SYSTEM of a PRIMARY/SECONDARY DOSE MONITORING COMBINATION shall be set to terminate IRRADIATION when the selected number of DOSE MONITOR UNITS has been reached; the SECONDARY DOSE MONITORING SYSTEM shall be set to terminate irradiation when the pre-selected number of DOSE MONITOR UNITS has been exceeded, either by not more than 10 % if a percentage margin is used, or by not more than the equivalent of 0,25 Gy absorbed dose at NTD if a fixed margin is used. Where there is a choice between fixed and percentage margins, the one providing the lesser difference shall be used.
- c) INTERLOCKS shall ensure that the system that has not caused TERMINATION OF IRRADIATION is tested between, or prior to, IRRADIATIONS to verify its capability to TERMINATE IRRADIATION.
- d) TERMINATION OF IRRADIATION may be achieved by means other than primary dosimetry systems (e.g. GANTRY angle), in which case the other means are considered as the primary termination system and the dosimetry system will provide secondary means of termination. The dosimetry system shall be set to TERMINATE IRRADIATION at a dose related value not greater than 110 % of the intended.

Compliance is checked as follows:

- a) TYPE TEST grade A – Statement regarding the DOSE MONITORING SYSTEMS and margins (where used).
- b) SITE TEST grade C – Principle: verification of the functioning of TERMINATION OF IRRADIATION by each system when the other is disabled. Test at one ENERGY for each RADIATION TYPE.

201.10.1.2.103.3 LEAKAGE RADIATION (excluding NEUTRONS) outside the area M

Example clause from Linac Safety standard

The ME EQUIPMENT shall be provided with PROTECTIVE SHIELDING that attenuates IONIZING RADIATION so that, in a plane circular surface of radius 2 m centred on and orthogonal to the REFERENCE AXIS at the ISOCENTRE, and excluding the area M, the ABSORBED DOSE due to LEAKAGE RADIATION, excluding NEUTRON RADIATION, shall not exceed

- a maximum of 0,2 %, and
- an average of 0,1 %,

of the maximum ABSORBED DOSE measured at the centre of the plane in a 10 cm x 10 cm RADIATION FIELD.

To avoid LEAKAGE RADIATION through the BLDs from influencing the measurements, the BLDs shall be closed to minimum aperture at central axis and, where necessary, suitable absorbing material added so that the area M is protected by a total of at least three TENTH-VALUE LAYERS from the X-RADIATION BEAM.

Compliance is checked as follows:

TYPE TEST grade B – Procedure:

- with axis 1 at 0°, 90° or 270°, and axis 4 at 0° (see Figure 201.108), determine points of high LEAKAGE RADIATION at all X-RADIATION ENERGIES and at the highest ENERGY of ELECTRON RADIATION. Perform RADIATION DETECTOR measurements at these points to obtain

60601-2-68: IGRT Equipment

- Proposing development of 2nd edition
- Important changes required to reflect modern equipment:
 - Non-isocentric equipment, 6 DoF movements
 - Imaging systems other than orthogonal kV x ray
 - Adaptive treatment, gating, tracking
 - Connectivity



61217: Coordinates, Movements and Scales

- US is leading development of 3rd edition
- First committee draft to be distributed for NC vote this fall
- Important changes reflecting modern design:
 - Non-isocentric equipment, 6 DoF movements
 - Revision triggered by issues around modern treatment couches for ion-beam accelerators, but will incorporate other updates and anticipate future changes also



62083: Safety of Treatment Planning Systems

- Switzerland is leading development of 3rd edition
- Second committee draft to be distributed for NC vote this fall
- Important changes reflecting modern design:
 - Increased use of imaging for planning
 - Design of equipment and patient model
 - Advanced calculation algorithms, beam model rather than data-based
 - Adaptive planning, gating and tracking



Role of US Technical Advisory Group

1. Review and recommend vote on New Work Item Proposals
2. Review, comment and recommend vote on Draft Standards
3. Recommend technical experts to serve on Working Groups
4. Technical Advisor (Chair of TAG) relays recommendations to USNC

