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

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St. Louis 1904:
palace of electricity

Structure of the IEC

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 ≠ 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

Collateral standards

60601-1 General Standard

More general requirements:

- 60601-1-2 Electromagnetic compatibility
- 60601-1-4 Usability
- 60601-1-8 Alarm systems
- 60601-1-9 Environmentally conscious design

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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
60601-2-68: 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

Thank You!