A MEDICAL PHYSICIST'S GUIDE TO THE INTERNATIONAL ELECTROTECHNICAL COMMISSION

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In the US, many of the requirements addressing the safety of radiation therapy equipment are published by the FDA or the NRC, or are promulgated by the states through their Health Departments. In many cases, specific requirements for performance and QA originate in standards published by the **International Electrotechnical Commission (IEC)**. The design of equipment for radiation therapy is likewise impacted a great deal by the IEC standards. The **American Association of Physicists in Medicine** participates in the development of these standards, and the contribution of AAPM members is essential to assure that the standards are scientifically and clinically meaningful.

The I.E.C.

The International Electrotechnical Commission is a standards-setting organization of approximately 50 member nations, with headquarters in Geneva, Switzerland. It came into existence in 1906, and consequently is celebrating 100 years of standards development this year.

The role of the IEC is to develop and promulgate standards for safety and performance of electrical devices, to assure uniformity throughout the world ("global harmonization"). The standards address a wide range of consumer and commercial devices ranging from toasters and shavers to bullet trains and power plants. Member nations participate through their own electrical standards committees (or National Committees). The stated object of the IEC is to "promote international cooperation on all questions concerning standardization in the electrical and electronic fields." To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications, and Guides.

The standards developed by the IEC are essentially adopted into law in many countries. For example, in Europe, the principal IEC safety standards are selected for "parallel voting" by CENELEC, the European electrical standards organization. When approved, they are assigned an "EN" number, and are adopted into law as written. However, it is up to EC members to enforce the provisions. If an EC member refers to an IEC standard in their "Medical Device Directive", the manufacturer must contract with a "notified body" to evaluate the device and determine its compliance with the standard.

In the US, IEC standards, or portions of them, are written into ANSI standards, FDA regulations, or NEMA guidelines. Not surprisingly, because manufacturers must comply with IEC standards to sell equipment in the EC, equipment sold in the US generally meets the IEC standards also.

The IEC consists of 200 technical committees and subcommittees that address each of the fields in which electrotechnical equipment is used. However, it is in the working groups that the actual development of standards takes place. Any member country can participate in the working groups, and most take advantage of this option. Because of the interest of manufacturers in the standards, most working groups are populated largely, if not entirely, by manufacturers' representatives. Consequently, the continued involvement of clinically oriented medical physicists is important to assure the relevance of IEC standards having to do with radiology and radiation oncology.

IEC Standards

An IEC international standard is defined as:

> "A normative document, developed according to consensus procedures, which has been approved by the IEC National Committee members of the responsible committee in accordance with Part 1 of the ISO/IEC Directives as a committee draft for vote and as a final draft International Standard and which has been published by the IEC Central Office."

A key aspect of this definition is indicated by use of the word "consensus". IEC standards represent the consensus of the national committees of member countries.

The IEC publishes several different types of standards:

Safety Standards

Many of the IEC's safety standards are organized in a hierarchical fashion, with a document called the General Standard at the top of the pyramid. The General Standard is numbered 60601-1, where the first "60" identifies it as an IEC standard (they are assigned numbers between 60000 and 79999) and the next "601" indicates that it is a report of TC62. The "-1" indicates its position at the top of the list.

A series of documents numbered 60601-1-X are called Collateral Standards and expand on certain generic issues. For example, IEC 60601-1-2 address electromagnetic compatibility, while IEC 60601-1-8 deals with alarm systems.

Documents numbered 60601-2-X are Particular Standards and define safety requirements for specific pieces of equipment. For example, IEC 60601-2-1 details safety requirements for medical accelerators operating in the range from 1 to 50 MeV. The numbering system is used to indicate that Particular Standards modify the General Standard. All of the clauses in a Particular Standard either modify, replace, or are additions to clauses of the General Standard. Examples of this are given below.

Additional safety standards are given simple 5-digit numbers, such as IEC 62083: Requirements for the safety of treatment planning systems. These safety standards stand independently from 60601-1, the General Standard, because the format of a particular standard is not appropriate.

Technical Reports

The IEC often publishes documents that address issues of performance rather than safety. Two good examples are IEC 60976, Medical electron accelerators: functional performance characteristics; and its companion document, IEC 60977, functional performance guideline. Technical reports are informative while standards are normative. As an example, IEC 60976 describes measurements and test procedures to be followed by the manufacturer of a linear accelerator. These procedures are to be followed to report relevant characteristics of operation, such as reproducibility of output, or range of motion of the collimator. It also suggests a format for the manufacturer to report the characteristics. IEC 60977 reproduces the recommended format and suggests acceptable values for each parameter.

The US National Committee

Each member nation participates in the IEC through its National Committee. The US National Committee is located at the offices of ANSI, in New York. The USNC Technical Advisor and representative to SC62C is Geoffrey Ibbott, Ph.D., of the US FDA. The USNC established a

technical advisory group (TAG) associated with subcommittee 62C. Dr. Ibbott presently chairs the TAG, and is a member of working group 1. Dr. Eric Woronowicz is a member of WG-2 and leads a small group to contribute to and review their standards, and Dr. Larry DeWerd is a member of WG-3 and leads a delegation that contributes to and reviews their standards.

Participation on the Working Group is an important responsibility, as the decisions made by the WG, and ultimately adopted by the IEC, influence the design of radiation therapy equipment sold all over the world. The AAPM contributes to support of the TAG and our participation on the working groups.

Technical Committee 62

TC62 is responsible for electrical equipment in medical practice. It has four subcommittees that address different areas of medicine:

Subcommittee 62A

Common aspects of electrical equipment used in medical practice are handled by SC62A. This subcommittee is responsible for developing and maintaining a technical report, 60788, which is a compilation of defined terms. The subcommittee also maintains an important safety standard, known as one of the "general standards", from which many other safety standards are derived. This standard, 60601-1, establishes requirements for basic electrical safety in medicine, and identifies aspects of essential performance, defined as necessary to assure a reasonable freedom from unacceptable risk. Some representative issues addressed by SC62A include safety signs and symbols, basic requirements for protection against electric shock (including wire gauges and insulation thicknesses), protection from mechanical hazards of moving parts, and protection from thermal hazards. The general standard also contains basic requirements for protection against radiation, including x and gamma rays, particulate radiation, microwaves, ultraviolet, infrared and laser radiation.

The standards written by other subcommittees modify the general standard, by amending its provisions or by adding new requirements.

The general standard has recently undergone a major revision to reflect a significant change in philosophy. Previously, the standard referred to "safety" as if it were a binary choice; either a device was safe or not. The 3rd edition of 60601-1 is now entitled "General requirements for basic safety and essential performance". The term "essential performance" is defined as "freedom from unacceptable risk". For some devices and the corresponding standards, this means a significant change in philosophy, but for radiation therapy equipment, it is likely that few changes, other than numbering, will be required.

Subcommittee 62D

This subcommittee is listed next because it handles medical non-radiological equipment such as electric beds and cardiac defibrillators. This subcommittee will not be discussed further as it has no relevance to the AAPM.

Subcommittee 62B

This subcommittee handles diagnostic imaging equipment. A selection of the standards developed recently by this committee and its working groups include the following:

- IEC 60336 Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots
- IEC 60522 Determination of the permanent filtration of X-ray tube assemblies

- IEC 60601-1-3 Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7 Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-28 Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-33 Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-2-44 Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

Subcommittee 62C

Of the many IEC committees, subcommittee 62C is responsible for equipment for radiation therapy, nuclear medicine, and radiation dosimetry. It has three working groups, of which WG-1 is responsible for radiation therapy equipment, WG-2 handles nuclear medicine equipment, and WG-3 deals with radiation dosimetry measurement equipment. All three WGs have US medical physicist members who attend working group meetings, and lead small delegations of US medical physicists who make up the technical advisory group (TAG) that advises the US National Committee on comments and votes on IEC documents. As Chair of subcommittee 62C, the author of this document has the most familiarity with the standards developed by this subcommittee, and therefore will spend more time describing the standards, of which there are 63.

Working Group 1

606-1-2-1. Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV

Probably the most comprehensive, far-reaching and influential recent publication of WG-1 is the second edition of IEC 60601-2-1 known as the Accelerator Safety Standard. This document dictates the design of important safety features of medical linear accelerators, including the functioning of the dosimetry system, the testing of interlocks, permitted levels of radiation leakage, and certain important characteristics of the radiation beams. This document was completed and published in 1998, and amended in 2002.

The accelerator standard is presently undergoing a revision to bring it in line with the 3rd edition of the general standard. Other proposed revisions will include changes to address portal imaging and on-board x-ray imaging systems.

IEC 60601-2-8. Medical electrical equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

This standard probably has more historical value than present impact, but it is kept up to date nonetheless. However, it won't be discussed further here.

IEC 60601-2-11. Medical electrical equipment - Part 2: Particular requirements for the safety of gamma beam therapy equipment

This is another historical standard, but a 2004 update extended it to multi-source cobalt units, such as the Gammaknife.

IEC 60601-2-17. Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

This standard was updated in 2005 to address remote-afterloading beta source devices, as were until recently used for IVBT. The standard is now being revised to comply with the 3rd edition of the general standard. The standard already establishes requirements for safety and essential performance. It sets limits on the emitted radiation while the source in the safe or is in transit, addresses the precision of source positioning, and limits the dose to the patient in the event of a treatment error.

IEC 60601-2-29, Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators

This safety standard is exactly parallel to the accelerator standard, but addresses conventional x-ray simulators. A problem has recently been pointed out; the standard does not address CT simulators. It is not clear at this point if the standard will be modified, or a new standard will be proposed for this purpose.

IEC 60976 and 60977, Performance Standards for Radiotherapy Accelerators.

IEC 60976 describes measurements and test procedures to be followed by the manufacturer of a linear accelerator. These procedures are to be followed to report relevant characteristics of operation, such as reproducibility of output, or range of motion of the collimator. New requirements included in an amendment published in 2000 address the performance of multi-element beam limiting devices (meBLDs, or multileaf collimators, for those unfamiliar with IEC-speak.) It also suggests a format for the manufacturer to report the characteristics. IEC 60977 reproduces the recommended format and suggests acceptable values for each parameter.

Both 60976 and 60977 are presently being amended to address the special requirements of equipment intended for IMRT.

IEC 61168, Radiotherapy simulators - Functional performance characteristics

IEC 61170, Radiotherapy simulators - Guidelines for functional performance characteristics

These documents, last revised in 1993, are exactly parallel to the accelerator performance standards, 60976 and 60977. Until a decision is made on how to handle CT simulators, there is little motivation to update these standards.

IEC 61217, Coordinates, Movements and Scales.

This standard, published by the IEC in 1996, standardizes the coordinate systems and scales to be used for radiation therapy equipment. The standard was amended in 2002 to include new language defining a patient coordinate system, together with matrices to enable transformation of coordinates to and from the DICOM coordinate system. This standard defines the so-called "IEC scales" and ensures that various pieces of radiation therapy equipment communicate gantry angles, field dimensions and other critical parameters accurately. Provisions are included that allow alternate coordinate and scale systems to be used (for example, for compatibility with older equipment in a department setting) as long as the IEC system is always available as an option and is always used for communications.

IEC 61859, Guidelines for radiotherapy treatment rooms design

The IEC decided to publish a safety standard to pull together requirements for the design of treatment rooms, from the perspective of the manufacturer of treatment equipment. This was felt to be necessary because some manufacturers provided turnkey installations including protective shielding and interlocks. This document encapsulates but does not supercede other national and international publications on shielding design.

IEC 62083, Safety of Radiotherapy Treatment Planning Systems.

Completed and published in 2000, this standard addresses features of software design intended to reduce the likelihood of incorrect data entry and misinterpretation of results. The standard also has been adopted by the IAEA and incorporated into a report to guide physicists in developing countries on selecting a treatment planning system and conducting acceptance tests.

IEC 61852, Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects

… and …

IEC 62266, Medical electrical equipment - Guidelines for implementation of DICOM in radiotherapy

Some years ago, the IEC made the commendable decision to cease work on its own standard for electronic data exchange, and officially adopt the DICOM standard. Several meetings were held at which a number of issues believed critical by WG-1 members were discussed with the members of the DICOM-RT working group, and consensus was reached. Ultimately, the IEC published guidance for implementation of the DICOM-RT objects, to familiarize readers with the origins of the objects, explain the meaning and interpretation of a conformance statement, and raise issues to consider when specifying and purchasing equipment. Technical report 61852 was published in 1998 and 62276 was published in 2002.

IEC 62274, Medical electrical equipment - Safety of radiotherapy record and verify systems

With the increased implementation of R&V systems in radiotherapy, the IEC felt it necessary to draft a safety standard defining the requirements for safety of these systems. The standard makes requirements for data exchange and checking between pieces of radiotherapy equipment.

Working Group 2

Specifics of the documents produced by this working group are not provided here, but can be made available on request.

IEC 60789, Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras

IEC 61303, Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance

IEC 61675-1, Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs

IEC 61675-2, Radionuclide imaging devices - Characteristics and test conditions - Part 2: Single photon emission computed tomographs

IEC 61675-3, Radionuclide imaging devices - Characteristics and test conditions - Part 3: Gamma camera based wholebody imaging systems

IEC 61948-1, Nuclear medicine instrumentation - Routine tests - Part 1: Radiation counting systems

IEC 61948-2, Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging

IEC 61948-3, Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs

Working Group 3

Specifics of the documents produced by this working group are not provided here, but can be made available on request.

IEC 60601-2-9. Medical electrical equipment - Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors

IEC 60580, Medical electrical equipment - Dose area product meters

IEC 60731, Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy

IEC 61267, Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

IEC 61674, Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging

IEC 61676, Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology

AAPM members who wish to contribute to the publications of the Working Group are encouraged to contact the undersigned. Be warned, however! These documents are complex, and are necessarily written to be both unambiguous and understood by people of many cultures and backgrounds. Review is not easy, but it is rewarding work, as one is aware that the result will have significant and long-lasting effects.

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