CIRMS Measurements for Radiation Therapy Applications (Tuesday, July 27 10:15 AM)

Larry A. DeWerd, Ph.D., FAAPM, University of Wisconsin, moderator

Presenting Authors:
B. Coursey, National Institutes of Standards and Technology, "Design and Use of the Wide Angle Free Air Chamber (WAFAC) for low energy brachytherapy seeds."
C. Soares, National Institutes of Standards and Technology, "Calibration Standards for Intravascular Applications"
J. Shobe, National Institutes of Standards and Technology, "Establishment of Absorbed Dose to Water Calibration at NIST"
L. A. DeWerd, University of Wisconsin, "Transfer of Absorbed Dose to Water Calibration to the ADCLs"
H. T. Heaton, Center for Devices and Radiological Health, "Regulatory Issues with Sources used in Radiation Therapy."

Educational objective: An understanding of equipment and methodology involved in the establishment of standards for radiation therapy applications.

DESCRIPTION OF CIRMS

The Council on Ionizing Radiation Measurements and Standards (CIRMS), incorporated in January 1993, is a non-profit and action-oriented society organized for educational and scientific purposes. The main objectives of CIRMS are advancement and dissemination of the physical measurements and standards needed for safe and effective applications of ionizing radiation. In particular, CIRMS represents users of ionizing radiation and radioactive sources engaged in medical radiation. CIRMS provides a forum for discussing ionizing radiation issues; identifying, defining and prioritizing needed work for standards; disseminating information on standards; and organizing workshops and meetings to advance ionizing radiation technology. CIRMS has been effective in coordinating the activities of federal, (e.g. NIST, NRC and FDA), state, (e.g. radiation control programs), and private sector, (e.g. hospitals, professional societies / AAPM), organizations concerned with applications of ionizing radiation and the related programs of physical measurements and standards laboratories. The National Institute of Standards and Technology (NIST) is heavily involved with this organization and considers its directives as statements of work to be completed. To accomplish its purposes, the Council functions through an annual meeting, through activities of committees and subcommittees, and through sponsorship of seminars and workshops. In addition, two NEEDS reports for standards, which outline the areas in which measurements and standards are apparently lacking, have been prepared by the Science and Technology Committee of CIRMS. The first report was published in January 1995 and the second in 1999. In the1999 report, 25 Measurement Program Descriptions (MPDs) have been identified that require concerted efforts from industry, government and the academic community. Each MPD describes a measurement-related need, a possible solution, and the impact of that solution. Details are provided regarding the technical nature of the solution, relationship to existing programs, technical opportunities, challenges and goals. Resources available and those needed to accomplish the programs are also indicated.

OUTLINE OF THE SYMPOSIUM

A presentation of the research and measurements made for standards for Medical Radiation Therapy Applications will be summarized addressing three major topics: Absorbed Dose to Water Calibration, Brachytherapy seed calibrations and calibrations for intravascular applications. Each of these standards is described in Measurement Program Descriptions (MPD), which are statements of requirements and the reasons for the measurements. The titles of the appropriate MPDs are A.4.1 Absorbed-Dose-to-Water Standards for Photon External Beam Radiation Therapy A.6 National Air Kerma Strength Standards for Brachytherapy Sources and A.7 Standardized Dosimetry for Intravascular Brachytherapy Sources.

THERAPEUTIC IONIZING RADIATION HISTORICAL STANDARDS

Therapeutic ionizing radiation is one of the common treatment modalities for cancer. Over half of all cancer patients undergo ionizing radiation treatment either for palliation or for cure (approximately 600,000 patients per year). Using large doses of radiation imply a dose that is accurately known and precisely delivered to the tumor. Radiation oncologists have been able to see clinically acceptable differences in the treatment of patients for variations as little as 5% in the delivered dose. By far the most common types of radiation presently used to treat cancers are photons and electrons. Both are most frequently produced by linear accelerators, although radioactive source teletherapy units still play a role for photon treatments. Photon-emitting radionuclides are the primary source of photons for brachytherapy treatments.

Historically the National Bureau of Standards (now National Institute of Standards and Technology [NIST]) played a major role in developing national standards for measuring the radiation used to treat patients. In the 1920s, the free air chamber was designed to measure the then-new radiation quantity exposure. Free air chambers with different dimensions were developed to cover the energy range from 10 to 300 keV. In the 1970s graphite cavity ionization chambers were developed to measure the exposure from ^{137}Cs and ^{60}Co. Like x-rays, the radium discovered by the Curies in 1898 was quickly used as a therapeutic agent for the treatment of cancer. Radium brachytherapy sources were used for the interstitial treatment of tumors. Newer radionuclides, e.g., ^{192}Ir and ^{125}I, have replaced radium for this use.

LOW ENERGY BRACHYTHERAPY SOURCE STANDARDS

With the development of improved methods of implanting brachytherapy sources in a precise manner for treating prostrate cancer, there has been a tremendous growth in the use of ^{125}I seeds for this modality. The lack of air kerma strength standards for these and other brachytherapy sources such as ^{103}Pd has slowed the implementation of the AAPM Task Group 43 report. Air kerma strength is strongly recommended rather than activity for calibrating these sources, since it has greater accuracy and is a more fundamental quantity. The recent change in brachytherapy ^{125}I source calibrations is a result of measurements made with the Wide Angle Free Air Chamber (WAFAC). The design and use of this free air chamber to measure low energy brachytherapy seeds, including ^{103}Pd will be given. A new and more accurate standard has been established with the WAFAC. This standard is being used to establish calibrations for the many new ^{125}I and ^{103}Pd sources being introduced in the market.

STANDARDS FOR RESTENOSIS APPLICATIONS

A new area of activity using brachytherapy sources is for the prevention of restenosis after balloon angioplasty. Approximately 40 percent of patients having angioplasty have a re-clogging of the arteries (restenosis) within six months. Studies show that doses of 10 Gy to 30 Gy appear to be effective in preventing restenosis. In these studies, radioactive sources are inserted into the artery through a catheter. These sources are in close proximity to the vessels so the determination of the dose at millimeter distances from the source is important. Methods to calibrate these sources at close distances are being addressed. The AAPM Task Group 60 has indicated the importance of calibration of such sources. The system for standardized dosimetry for intravascular brachytherapy sources will be discussed, emphasizing the developmental work which has been performed and which continues at NIST. Calibration methods for these sources are evolving almost as fast as the sources are being developed for this application. The challenges are the very close distances to the very small sources at which dosimetry is required, and the large number of isotopes and source geometries now under active investigation.

ABSORBED DOSE TO WATER STANDARDS

Historically the ion chambers used to measure the output of radiation therapy machines were calibrated free in air in terms of an exposure (or more recently air kerma) from a ^{60}Co unit. Then a protocol, such as TG-21, is used to convert the measurement to absorbed dose to tissue. A more straight forward approach would be to calibrate the ion chamber in a water phantom in terms of absorbed dose to water since this is reasonably close to the desired absorbed dose to tissue. Thus an absorbed dose to water standard based on a water calorimeter was developed. NIST and the ADCLs now provide an absorbed dose to water calibration factor for ion chambers immersed in water phantoms.

Discussion of the measurements to determine an absorbed dose to water in-phantom calibration, in support of AAPMs new protocol written by TG-51, will be presented. NISTs role was to establish the U.S. standard linking the Domen water calorimeter to measurements made with ionization chambers. This process will be discussed along with results from recent international comparisons. The transfer of this standard to the ADCLs will also be discussed in line with the AAPM task group for this purpose. Also presented will be the results from the ADCL round-robin proficiency test conducted by NIST.

REGULATORY ISSUES IN RADIATION THERAPY APPLICATIONS

Finally a review of the regulatory issues with sources used in radiation therapy will touch on three areas of regulatory concern from a physics point of view: (1) IDE and PMA requirements for studies involving intravascular brachytherapy, (2) brachytherapy sources with emphasis on those low energy sources used to treat prostrate cancer, and (3) well ionization chambers. While this talk will focus on the issues from the FDA/CDRH point of view, the NRC also has concerns in the areas that will be mentioned.

The main objectives for the regulatory concerns are:

1) Medical physicists should review IDE, PMA and 510(k) submissions using brachytherapy sources before being sent to the FDA. It is important to ensure that dosimetry and physics issues are adequately addressed.
2) Before participating in a study using any radiation to prevent restenosis in the cardiovascular system, it is necessary to have institutional IRB approval and the study must have a FDA approved IDE.
3) One of FDA/CDRHs concerns with physics issues is that the user can adequately determine the treatment dose for brachytherapy sources calibrated with new national standards.