



American Association of Physicists in Medicine

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April 7, 2010

Rep. Frank Pallone, Jr.
House of Representatives
Chair Subcommittee on Health
c/o Sarah Despres
237 Cannon Building
Washington, D.C. 20515-3006

Re: Follow up to the February 26, 2010 Hearing on “Radiation Use in Medicine: An Overview of the Issues”

Dear Chairman Pallone:

On behalf of the American Association of Physicists in Medicine¹ (AAPM) and all patients who currently benefit from and who will benefit from improvements in the medical use of radiation, thank you very much for calling the very important hearing held on February 26, 2010. We realize that you may have raised more questions than were answered and we would like to comment on a few points that were discussed during the hearing.

The Medical Team. As discussed at the hearing, the team delivering medical radiation includes the physician, medical physicist, radiologic technologist and (in radiation therapy) a medical dosimetrist. There are significant differences between diagnostic imaging procedures and radiation therapy procedures that utilize medical radiation. In addition, the technology development and implementation process from manufacturer to clinical use is critical to the use of medical radiation. This involves engineers, product managers, medical physicists and regulators. The attached graphic briefly summarizes the technology development, the procedure implementation process and the clinical process flow in the diagnostic and therapeutic use of medical radiation. We would be pleased to provide further detail, in cooperation with other team members.

¹ The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

Qualifications required for radiation team members are state regulated and widely variable. In many states, most of the team members including the Medical Physicist, Radiation Therapist and Medical Dosimetrist, have no specific qualifications required.² The *Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Bill of 2009* - H.R. 3652 will require that minimum standards for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures be established. The intent of the bill is to cover all subspecialties of clinical medical physics.

We believe that passage of this bill will enhance patient safety in the use of medical radiation. Thus, we urge that ALL individuals involved in these procedures be included in this legislation. However, H.R. 3652 currently excludes advanced imaging modalities, because, as we understand it per the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) (P. L. 110-275), the specifics of personnel qualifications are left up to the accrediting body and may not have to meet any other standard. Thus the minimum qualifications in accordance with H.R. 3652 might not be required for the advanced imaging modalities (nuclear medicine, magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET)) covered under MIPPA for facilities to become accredited. We remain concerned about this exclusion.

Accreditation is very important and perhaps is the mechanism that could ensure that qualified individuals are staffed in appropriate numbers, and perform procedures based on national consensus guidelines. Accreditation must be tied to reimbursement in a hybrid to the *Mammography Quality Standards Act of 1992*³ (MQSA) (P.L. 102-539) and MIPPA models. MQSA, as you suggested is much more prescriptive and MIPPA, much less so. Possibly, the required qualifications for individuals to deliver radiation should be mandatory by federal legislation. This is consistent with the CARE bill. However currently, H.R. 3652 has exclusion for MIPPA and each of the three accrediting bodies, deemed by Center for Medicare & Medicaid Services (CMS), set their own personnel standards. This exclusion was inserted prior to the granting of deemed status by CMS to accrediting bodies.

It is clear now that MIPPA as currently in place does NOT require consistent qualifications for individuals who are involved in the delivery of medical radiation especially for medical physicists. Thus passage of H.R. 3652 and additional legislation, similar to that for MQSA for the personnel qualifications, requirements is necessary. The minimum number of qualified individuals and the specific practice guidelines followed could be specified by legislation, but not quantified in the legislation. This means that it would be expected that the medical community adopt consensus standards of practice by which uniform national accrediting would be accomplished. Subsequently, a robust combination of mandatory qualifications and consistent accreditation, required for CMS payment, would improve patient safety and care.

² There are specific requirements for individuals to use radioactive materials defined by the NRC and Agreement States. These address the use of radioactive materials only (not x-ray producing equipment) and do not specify the credentials to practice.

³ By MQSA we mean as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

Dr. Michael Hagan of the VA mentioned a technical practice review performed by the Radiologic Physics Center that went beyond an accreditation review and revealed a substantial number of technical deficiencies that could impact patient care. While the charter of the Radiologic Physics Center limits their work to practices involved in NCI cooperative clinical trials, we feel that technical reviews similar to those could provide an independent credentialing process or be an integral part of an improved accreditation process, allowing for objective and thorough review of the imaging or radiation therapy practice technical quality. Specifically, practices would be required to demonstrate that they deliver medical radiation accurately and safely prior to being able to bill for a given procedure. AAPM is currently reviewing mechanisms to establish centers for radiologic physics that would serve this purpose nationally.

Event reporting in a national system is essential, and it must be non-punitive and able to collect potential and actual event data completely and efficiently. AAPM is currently working with the U.S. Food and Drug Administration (FDA) and others to discuss possible mechanisms for establishing such a system. It is important to note that any national system will need to be coordinated with the states, potentially through the Conference of Radiation Control Program Directors (CRCPD). We recognize that there may be potential implications in accordance with the *Health Insurance Portability and Accountability Act (HIPAA) of 1996* (P.L.104-191) legislation. It is only with a unified and consistent national system that we can have early warning in order to take action before catastrophic adverse events occur.

Medical radiation equipment review is also under scrutiny. We feel that the FDA 510(k) process can be substantially enhanced by supplementing the FDA review with independent expert technical assessments. Such assessments, for example, those provided potentially by an independent Technology Assessment Institute, would provide timely, knowledgeable, and objective reviews that could be incorporated into the FDA review process and would include essential safety aspects and specific clinical and user integration evaluations for the technology under review. This potentially iterative approach could include the opportunity for expert/failsafe systems to be built in and recognized in medical equipment. Use of objective external expert reviews could assist FDA with the immense task of having sufficient expertise to assess every type of equipment for every application.

In summary, once again, AAPM thanks you and your subcommittee for your interest in the use of radiation in medicine. We believe the major points raised at the hearing and in testimony include:

- national recognition of required radiation team member qualifications;
- improved and consistent accreditation processes to ensure qualified people in appropriate staffing numbers perform medical radiation procedures following national consensus best, safe practices;
- a consistent and accessible national event reporting/recording system; and
- enhancement of the FDA 510k process with objective technical support.

Thank you and the members of the subcommittee for recognizing and stressing the immense value of the use of medical radiation in this hearing and for engaging the medical community

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with hope that this dialogue will help all of us move toward improved patient safety and even better results with the use of medical radiation.

We would be pleased to continue discussion and engage further in any manner that has the potential to facilitate improvements in patient safety, ensure quality medical care, and the quality of the medical use of radiation. Please contact Lynne Fairobent, Manager of Legislative and Regulatory Affairs at lynne@aapm.org or 301-209-3364 or me if you have additional questions.

Sincerely,



Michael G. Herman, Ph.D., FAAPM, FACMP

1 Attachment

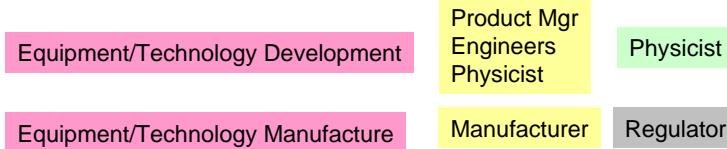


The Medical Radiation Process Overview

Roles of Team members, Manufacturers, Regulatory agencies



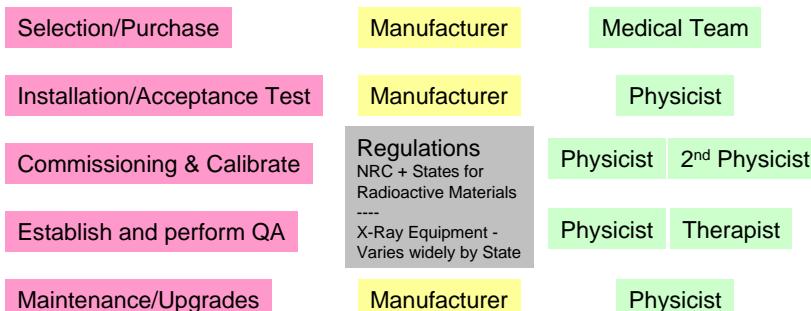
At Manufacturer



At Medical Institution New Process/ Procedure Implementation



At Medical Institution New Equipment Implementation



At Medical Institution Patient Specific Procedure

Patient Referred for Medical Radiation

Referring Physician

Diagnostic Imaging

Registration

Desk

Image Preparation

Technologist

Radiologic Imaging Procedure

Technologist Physician

Images Interpreted

Physician

Patient Related Dose/QA

Regulations
Some Federal (MQSA)
Other Varies widely by State

Physician

Therapy Needed

Surgery, Medical Oncology,
Interventional Radiology/Cardiology

Radiation Therapy

Consultation

Physician

Regulations
Limited, varies widely by State
Federal only NRC for materials

Simulation

Physician, Therapist
Dosimetrist, Physicist

Dosimetric Planning

Physician, Dosimetrist,
Physicist

Treatment Verification/QA

Therapist, Physician
Dosimetrist

Treatment Delivery

Therapist (Physician, Physician)

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