Food and Drug Administration Public Meeting June 9-10:

Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation

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Quality Assurance for patient safety

- A shared responsibility
  - Manufacturers
  - User Community
    - Physicians, Medical Physicists, Radiation Therapists, Dosimetrists, Administration
  - Regulatory Authorities
    - FDA, NRC
  - CRCPD
  - US Congress

Responsibility for QA programs

- The ultimate responsibility for appropriate QA of radiation therapy devices rests with the facility using the devices.

- The facility's Qualified Medical Physicist (QMP) is best prepared to design and oversee a QA program that is appropriate to the technology being used and the clinical scope of services rendered with the technology.

Manufacturers

- The device manufacturers should provide clear guidance to the facility's QMP on how the equipment and software function and on how to perform tests in accordance with published QA guidelines (AAPM Task Group reports & others).

- The device manufacturers should provide clear and thorough documentation of the scope of validation testing, the results of this testing, and known limitations of the system.

- The QA requirements for a new device should be a required part of the pre-market clearance.

Manufacturers - documentation

- Technical user manuals should be available to <u>all</u> users of a device
  - Independent of how the device was purchased (e.g., direct from OEM or through a third party, new or used)
  - Independent of whether the facility maintains an ongoing service agreement with the manufacturer.
  - Technical safety bulletins should be communicated in a timely manner.

Consistent standard for QA?

- There is no requirement for consistency in QA programs across the country for specific devices.
- Guidelines are published by the AAPM in the form of Task Group reports.
- However, these guidelines often lack clear prioritization and are frequently not published until a given technology has matured.
  - Note, some states have incorporated portions of these AAPM reports into regulation, and others have not.

Result: Wide variation in QA programs for similar technology and clinical services.

<u>Need</u>: Consistent Practice Standards

- Medical Physics Practice Standards would ensure a consistent minimum standard across the US for quality assurance and patient safety – these could be mandated.

- Such standards should be concise and should specify the minimum level of QA for specific technologies and clinical applications.

- The development of these standards should be led by the AAPM in collaboration with other professional societies.

QA and the FDA

- The role of the FDA could be enhanced by:
  - Requiring the manufacturers to demonstrate compliance with, and support for, the consensus QA standards published by the AAPM and supported by other societies and accreditation entities.
  - Requiring the manufacturers to adopt the terminology recommended by the professional societies – avoiding brand-specific labels and terminology for core QA procedures. *Quality assurance is a patient safety matter, not a sales differentiator*.
  - Verifying that adequate software tools are available to users to perform the necessary quality assurance.

QA and Congress

- Congress could help by:
  - Requiring providers to support QA programs by providing appropriate resources (staffing levels, access time for testing of the devices, adequate test instrumentation, appropriate authority for the QMP to act when performance is outside the stated tolerance, etc).
  - Ensuring that providers are properly reimbursed for the cost of supporting comprehensive QA programs.

QA and Congress (continued)

- Congress could help by:
  - Requiring accreditation of clinical practices, using the Medical Physics Practice Standards as a basis for accreditation.
  - Passing the CARE Act (H.R. 3652) to ensure that staff are properly trained.

Reporting – benefits to QA programs

- A central reporting repository would greatly enhance patient safety by allowing all stakeholders to learn from each other and implement process / QA improvements based on that knowledge.

- Congressman Markey's questions of 3/15/2010

Summary

- *A culture of safety requires <u>all</u> stakeholders to take responsibility for their part:*

    – Professional societies to develop consistent practice standards

    – Manufacturers to provide clear reports of lessons learned in validation testing and specify the QA requirements for new devices

    – FDA to require manufacturers to follow consensus QA programs and terminology

Summary (continued)

- *A culture of safety requires <u>all</u> stakeholders to take responsibility for their part:*
    - Congress to require facilities to provide the resources needed for an effective QA program (accreditation), and ensure staff are properly trained (H.R. 3652 - CARE Act)
    - Clinical facilities to provide the resources needed for an appropriate QA program
    - Creation of an easy to use national event reporting system