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July 15, 2010

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Docket No. FDA–2010–N–0217**

The American Association of Physicists in Medicine (AAPM)[1] is pleased to provide the following comments in response to the May 7, 2010 Federal Register Notice (FRN)(75FR25279) regarding ***Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation; Public Meeting; Request for Comments***. AAPM appreciated the opportunity to present oral comments during the June 9-10, 2010 meeting.

These comments reflect responses to the questions posed in the Federal Register Notice. Also attached are the slides presented during the meeting on behalf of AAPM.

In general, AAPM believes that:

1. 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.
2. Accreditation is very important and perhaps is the mechanism that could ensure that

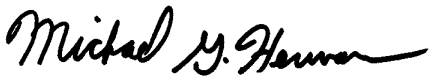
[1] The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics; a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional 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. Food and Drug Administration, the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

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 (MQSA) (P.L. 102-539) and Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P. L. 110-275) MIPPA models.

3. Supplementing the FDA review with independent expert technical assessments can substantially enhance the FDA 510(k) process.
4. Technical reviews similar to those conducted by the Radiologic Physics Center for practices involved in NCI cooperative clinical trials 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.
5. National recognition of required radiation team member qualifications is essential.

If you have questions, please contact me or Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or lynne@aapm.org

Sincerely,



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

Attachments

Attachment 1

Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation; Public Meeting; June 9-10 Request for Comments

II. Questions for Comment

A. Device Improvements and Reporting

1. Describe issues with misadministrations and your suggestions to address the safety issues.

Misadministrations, errors and accidents occur usually from a combination or sequence of relatively low probability events. In these cases, the complex system (including the technology [hardware plus software] and the human(s)) is unable to recognize or correct for the low probability sequence of events notes. A number of the questions below deal with specific sub parts of this more general question. A combination of better hardware/software safety systems built into the technology, plus properly educated and experienced team members (radiation oncologists, radiologic technologists [RT(T)], certified medical dosimetrists [CMD], qualified medical physicists [QMP]), plus established standard operating procedures for specific procedures (consensus practice guidance) [that is followed by the team] will improve safety. In addition to this, potential and actual events must be reported uniformly, completely and efficiently, nationwide, to allow us to learn as quickly as possible about patterns and potential catastrophic failures. Reported data must include initial cause analysis and a standard set of parameters and information, so that it can be quantitatively analyzed. Disseminating knowledge on error conditions and solutions is critical, and this must be done in a timely manner.

2. Are there any hardware and software features that manufacturers can build into radiation therapy devices to reduce underexposures, overexposures, or misaligned exposures to ionizing radiation during radiation therapy?

There are features that can be further developed to allow hardware and software to sense or determine out of tolerance conditions and warn the operator. The hardware is computer controlled and operates with complex software. At certain points in the delivery process, checks against reference conditions for hardware and software could be imposed. Hardware specific/generic self-testing to a large extent already exists. The enhancements discussed here would check for patient specific tolerance conditions that might be exceeded. This may include for example, if any field is corrupted in the transfer of information from the treatment planning system to the Record-and-Verify delivery system, a new download should be required or a flag that alerts the user and identifies the problem.

Any error messages generated must clearly (and uniformly) inform the users as to the problem. Generic messages that indicate a problem, but nothing specific can add to risks. Together manufacturers, users and others should work to create standards for communicating critical errors during the use of this equipment.

Manufacturers could provide formatted output at various points in the radiation treatment process to allow easy second checking of parameters.

3. What techniques do you recommend for improving therapists attention (e.g., a dead-man switch to assure operator attention). Should efforts to improve device safety features include: incorporation of access controls and audit capabilities into equipment to identify the specific user(s) of the device during any particular treatment? If so, why, and what access controls and audit capabilities should be incorporated? If not, why not?

Additional mechanisms requiring operator interaction should be considered. An example could be a requirement that the radiologic technologists (RT(T)) review and acknowledge certain actions at certain intervals that could be pre-programmed into the operating software. These could be generic points or could be potentially dependent on the specifics of the treatment. The higher risk procedures would have these in place at key points.

Access control to the system already exists to a large extent in (all) modern systems. Users must access control by password and must already have rights to perform given procedures. Usually any changes in settings also require user with rights and a password. In most systems the level of password protection is a custom setting, configurable by the administrative user at a given facility. Thus the password requirement, while available, might not be enforced or used. Enforcing specific user rights per type of user could improve safety. One possibility is to require use of access and change control management to treatment delivery technology in a standardized manner.

Working with attention to the task at hand is also a general cultural issue applying to all individuals involved in the workflow for radiation therapy. Learning from other industries or fields how to improve the culture of attention could help.

Attention to detail may also be related to distractions that occur in the immediate work area, causing attention to drift. At the Safety in Radiation Therapy meeting in Miami - June 24-25, 93% of the 300 plus member audience responded that the treatment console was somewhat or significantly prone to distractions.

Human factors analysis of system usage that would include efforts to improve awareness and attention to critical functions could be included in the manufacturing and/or facility design process.

4. If certain changes are desirable as additional safeguards for the devices, how feasible is it to retrofit existing units in the field?

Depending on the vintage of the system being retrofitted, this could be challenging or impossible. For systems that would only require software retrofit, it should be feasible. These should be software patches. It is important that adequate testing be performed to make sure that the additional safeguards are in fact effective and work as intended.

5. Should manufacturers standardize their display format to ensure that treatment settings, protocols, and collimator positions are displayed taking human factors into consideration and are recorded for physician review?

Yes, this could be done and it would be potentially useful for a standard display format to be developed (International Electrotechnical Commission (IEC)/American National Standards Institute **(**ANSI), etc.). This should at least be done for certain major items that are uniform to all manufacturers at the control console. There are certain types of information that should always be displayed (e.g., moving hardware, dose)
Control settings are already recorded in all modern systems that utilize record and verification software. These are available for review at any time as or after they occur. It might also be possible to develop a minimum standardized report of key information that could be reviewed quickly by a physicist, physician or other team member.

6. Should manufacturers submit more data to FDA as part of their premarket submissions for approval or clearance of devices, related to the safety of these devices? If so, why, and what data should be submitted? If not, why not?

Yes. AAPM believes that any additional submission requirements should be discussed between manufacturers, users and FDA to develop a consistent and meaningful minimum standard data set for submission. Not only is it important to have the information submitted, it is equally important that individuals or teams review the information who are expert in the safety aspects and operations of the treatment delivery process. To this end organizations such as AAPM have begun to develop lists of experts for given technologies and procedures who can provide expert review, should it be requested. Such expert reviewers could also be contained in a more formal technology assessment entity. AAPM has proposed a technology assessment institute with this type of review as one charge of a Technology Assessment Institute (TAI).

Additional information could include:

1. An expert user evaluation report that is also created as part of the FDA evaluation.
2. Detailed information about the manufacturer's user training process. This information should describe in detail:
    a. Any quality assurance (QA) devices or techniques be provided with treatment equipment or as part of the training process;

b. How these devices and techniques relate to existing Nuclear Regulatory Commission (NRC) regulations, State requirements or AAPM recommendations;
c. The exact testing performed at their beta test sites;
d. A safety profile and analysis performed by their clinical beta sites; and
e. Signed documentation from the beta test sites.

An ideal model for a premarket submission would require use of the device under simulated clinical circumstances (e.g., treatments are delivered to phantoms rather than people but they're delivered by therapists, not company engineers). The work could start with a mock commissioning performed by people who are potential users. The people running the reliability tests should be drawn from a pool of clinical users and the plans that are run should be clinically realistic plans. A stripped down conceptual model for this is the work of the Radiological Physics Center, which performs numerous on-site 'audits' of facilities that are involved in National Cancer Institute (NCI)-funded national protocols. In the new equipment situation, the reviewers would go to the manufacturer's facility to conduct the tests.

7. Should there be a mandatory ''timeout'' built into the equipment, similar to what already has been implemented for surgical procedures, to confirm that all settings for the equipment are correct and allow adequate time for QA? If not, why not?

The use of the concept of a "timeout" is already an accepted practice in many areas of medicine. There is no reason to believe this should not be extended to radiation therapy. In fact, many programs/departments already voluntarily utilize the concept of "timeout" before beginning therapeutic treatments mainly those that use radioactive materials (Gamma Knife, high-dose rate (HDR brachytherapy). Some departments also do this for high dose external beam procedures like stereotactic body radiotherapy (SBRT). The content of the timeout should be configurable to the department's process. Results from the audience poll at the Safety in Radiation Therapy meeting in Miami -June 24-25 meeting suggested that 72% felt a timeout should be mandatory, 24% felt timeouts should be required for procedures above a set complexity or risk threshold.

From the manufacturing side, it might be useful to force such a timeout through the operating hardware/software, where a certain final interlock condition must be cleared after the treatment team makes one final review of the pre-treatment conditions. Entry of identification or passwords of one of more individuals could be required to proceed with the treatment. The specific requirements could be different for specific procedures depending on complexity.

8. Should manufacturers provide better instructions and specifics (i.e., QA methodology) for acceptance testing and/or commissioning due to new and/or unique features/capabilities? If so, why and what should be included?

Manufacturers already provide very specific acceptance testing documentation for treatment delivery. The planning systems also have very specific commissioning guidance from the manufacturer.

The commissioning process is the responsibility of the QMP. Guidance from the manufacturer is important. However the following should be considered:

- Guidance given should be provided in a standardized format by all manufacturers to facilitate safe and uniform adoption and use.
- New features should have standardized acceptance and commissioning procedures.
- Guidance should be developed in cooperation with the clinical beta sites and relevant professional organizations.
- Communication and cooperability between systems of different manufacturers is crucial.

Manufacturers should provide:

- users with specific information about conditions under which the equipment was tested.
- guidance for additional tests that may be performed to further characterize the system.
- hands-on training, either individually or in partnership with professional organizations such as the AAPM.

9. Other than requiring a facility to report to FDA, how can FDA ensure that facilities report to FDA significant under-doses and over-doses? Should there be a quantitative metric used to define a medical event similar to that used by the Nuclear Regulatory Commission (e.g. +/- 20% variation from intended dose)?

Establishing thresholds for reporting as a patient safety "event" or as important information to add to the database for others to learn from is very important. Everything should be done to facilitate complete reporting of as much useful and standardized information as possible. As for a threshold beyond which a patient safety event is defined, this should be determined carefully and in cooperation with users and associations.

Yes, data on significant-under- and over-doses are essential to conduct analyses, make assessments, inform the community, and make improvements. We agree that there should be a centralized repository for this type of data. The system must provide the following for all actual and potential adverse events in the medical use of radiation by:

- Central reporting by medical staff (including radiation therapy physicians,

medical physicists, radiation therapists, dosimetrists, others), manufacturers and others in a complete and consistent manner,
- Search capability to identify patterns, risks and corrective actions, and
- Independence from any regulatory entity reports.

From the FDA perspective, there must be a straightforward, efficient and complete mechanism that all users of any equipment can report potential or actual events. This must be universally accessible (possibly through FDA or directly through a standard interface integrated into all manufacturers' products) and easy to use.

There should be quantitative metrics and standard terms for the data to be useful for analysis. In addition, the ability to analyze the data for patterns and develop appropriate actions is a significant undertaking and must be part of any national system.

Note that specific limits or trigger levels must be determined carefully. Occurrences reported in such a system must be distinguished from Medical Events, which have a separate and specific definition.

AAPM recommends that there be a public meeting of all stakeholders and regulatory agencies to solicit input as to the appropriate metric and terminology to be adopted.

10. What prevents users from participating in voluntary reporting?

Many users are not aware that they can report an event to the FDA. They may be unsure of the value of reporting the data. No standard mechanism or system exists to intake the data. It is not easy or efficient to do the reporting. It is not obvious to users that reporting has led to improved outcome or recognition of potential error conditions. Perhaps most importantly, legal liability protections are not strong enough; to achieve a high level of reporting, strong legal protections must be implemented.

AAPM believes that the definition of medical event should be uniform across radiation treatments. We also believe that the stakeholder community should have an opportunity to work with the regulatory authorities to establish the definition of a medical event that would be uniformly applied. It is possible that the definition of medical error may be procedure specific, but should remain consistent across the country. There are various models (NRC, some states, FDA and internationally (e.g., the International Atomic Energy Agency [IAEA]) that exist. These differ from each other but could serve as a beginning for developing a uniform system.

Again, events as are being discussed may not rise to the level of medical event, but still should be reported. Definitions should be expanded to include events that do not cause harm to the patient, but have the potential to do so, distinguishing between medical events and those that are significant enough to be reported but are not medical events.

11. How can FDA encourage reporting and prevent workarounds even when no clinically significant adverse event occurs?

Create a uniform, efficient and standardized system, with clear definitions that make it very easy to enter complete data. Partner with manufacturers to make the reporting system as available and consistent as possible. Make the system anonymous and non-punitive. Require input for events above some threshold and reward input for all other events that could help improve safety. The FDA can partner with radiation therapy organizations and other regulatory groups/agencies to find a common solution. The national system must be set up in such a way as to be independent of any reporting entity to prevent bias in the data reported. The database should be established such that no patient identification is included in the reports submitted to the reporting entity.

The impact of the radiation exposure, the risks and effects are the same for a similar dose, no matter what the source of the radiation was – whether radioactive materials or resulting from the operation of radiation-producing equipment. Therefore, it is important that any national system will need to be coordinated with the states, potentially through the Conference of Radiation Control Program Directors (CRCPD). 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.

The important requirements are that the system allows all of us to learn from actual and potential adverse events in the medical use of radiation by:

- allowing central reporting by medical staff (including radiation therapy physicians, medical physicists, radiation therapists, dosimetrists, others), manufacturers and others in a complete and consistent manner,
- requiring input for events above some threshold.
- rewarding input for all other events that could help improve safety.
- providing search capability to identify patterns, risks and corrective actions and to inform the community,
- using a well-defined taxonomy for events, and
- requiring a partnership between all involved (federal and state government, manufacturers, users, patient advocates).

B. User Training

1. Should manufacturers provide training to ensure equipment users have adequate understanding of equipment capabilities, operating principles for the technology, general information about patient dose, and specific dose-related equipment features? If so, why, and what training should be provided? If not, why not?

Manufacturers should educate users on the equipment capabilities of their technology. This process should guarantee that the users understand all operational issues related to their clinical use of the devices. User training should be an integral component of a system purchase – **not** an optional line item. The training materials (e.g., User's Manuals) should be available on-line to all users, regardless of whether the clinic pays for a maintenance/service contract through the manufacturer. Many clinics purchase used/refurbished machines through third-party service companies, and find it difficult to obtain the appropriate User's Manuals from the manufacturers.

Manufacturers must anticipate situations where the exact application of new dose-related equipment features may be applied in ways they have not anticipated. It is important that the training process include a discussion of the QA procedure(s) they recommend for guaranteeing safe use of these features for their intended application.

General information about patient dose should not be part of the user training provided by the manufacturer. This information should be obtained as part of the training and education of the individual team members respective to their specific role (RT(T), CMD, QMP, Physician). The type of education and experience recommended in H.R. 3652, The *Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Bill of 2010* will ensure that individual team members (excluding physicians) will have complete and consistent education and clinical training/experience and certification in their specific field (therapist, dosimetrist and physicist). The manufacturers should build on this core training to provide technology specific additional education. This can only be effective if the individuals meet qualification competencies as described in reference to H.R. 3652.

It is important to build an evaluation process into manufacturer user training. The manufacturer should construct evaluation forms for their trainers, and they should provided them to the facility administrator for completion by the departmental staff attending the training sessions. These forms should be mailed to the appropriate representative of the manufacturer for review. The radiation therapy professional societies should devise an evaluation procedure for the institution being trained. This evaluation procedure should document information like attendance and general availability of personnel during the training process.

Measures of competency should also be included in this evaluation process (see the description of training modules in the answer to question 3 below). If equipment is being used clinically, it is very difficult or impossible for the trainer to provide adequate training and for the user to learn the equipment.

Manufacturers should develop "simulation training" programs, whereby failures are simulate as a clinical procedure, and used for assessment of the clinical team members' response to the simulated failure. That is, the assessment is made according to their recognition of the failure and their appropriate actions.

2. If manufacturers provide such training, which personnel should receive it? In your response, please consider dosimetrists, physicists, radiation therapists or technologists in other specialties and departmental administrators as well as physicians in all medical specialties who may operate radiation therapeutic equipment.

No matter who provides the training, the specific individuals that need the training will vary depending on the specific equipment and use. For each technology and in coordination with professional societies, manufacturers should define the required initial and ongoing training for each team member. There may also be cases where administrators/managers should be educated on some aspects of the treatment planning and delivery technology (although this may not be as high a priority).

For example, implementation of treatment planning software should include dosimetrists, physicists, and physicians. Radiation therapy delivery equipment training should include therapists and physicists. Other personnel such as physicians and departmental administrators should be aware of the capabilities of the system and of any additional equipment and time that is needed to support adequate commissioning of the system.

If the equipment is a CT-simulator, the technologist must be trained. For a treatment device, the relevant personnel are the individuals listed above. Physicians from other medical specialties should not require training on the operation of radiation treatment equipment. However, there could be exceptions to this statement. Departmental administrators should not need training on the operation of the equipment. When the record and verify system is integrated into the treatment unit, training of individuals involved in billing might be necessary.

3. If manufacturers provide such training, what is the most effective timing for a new installation and how frequently should it be repeated for optimum implementation? Should manufacturers recommend an internal training program for use by the facility to insure continued staff competence?

Timing of the training process is complicated by a number of factors. The critical factor for the timing of the user training process is the training of the individuals (RT(T))

responsible for treating the patient. It is important that this training occur as near as possible to the time of treating the first patient. Ideally, the manufacturer's training representative should be available when the first treatment is undertaken. In some cases, additional training might be necessary well in advance to the start of treatment. This training is needed to guarantee that the equipment commissioning process is performed efficiently and correctly. It is possible to have the manufacturer's equipment installation team provide this portion of the training for the medical physics staff. Competencies should be created by the department – or potentially in cooperation of professional societies. Prior to the start of this training, the manufacturer should provide clear documentation of their user training process. It is the responsibility of the equipment purchaser to negotiate appropriate modifications of this program to better fit the training to their particular situation or to accommodate new information available in the peer-reviewed literature or in other pertinent reports.

Training should be provided annually for maintaining skills and learning about enhancements. Internal or web-based education could be effective for this task. It may be desirable for manufacturers to design training modules directly into the software. For example, in a treatment planning system example "patients" and a "find the error" challenges, would allow clinics to judge how familiar each user is with the system, and could become the basis for annual competency evaluations performed and overseen by the clinical team.

Having a formal program for introducing new personnel to the equipment is essential. This program may use the local qualified medical physicist and therapist to perform the training. However, in some situations there may be no local expert (e.g., someone leaves their position suddenly), and the manufacturer must be contacted to provide the training. This type of emergency situation requires the manufacturer to react quickly to this. Departmental administrators must be aware of the critical role they play in guaranteeing that training is obtained from the manufacturer, or implemented internally, whenever staff changes occur.

4. For software patches and upgrades, how is the software tested for hazard analysis, verification and validation? Should manufacturers perform additional testing to adequately test software patches?

Yes, upgrade and patch testing is the ultimate responsibility of the end user (e.g., the qualified medical physicist). However, There could be different levels of action with "additional testing" required for some situations. The aforementioned Technology Assessment Institute could be utilized for such situations.

In general, most facilities have a program in place to validate upgrades and patches. Each facility should test patches/upgrades before allowing them into clinical use. Nonetheless, the manufacturer must also thoroughly test the patches and upgrades prior to release. The manufacturer and the institution must then allow adequate time for the

patch to be tested locally. Depending on the complexity of the new software, this might take a few hours or a few weeks. Therefore, the existing system must be able to function after the installation of the new software until the new software is fully commissioned.

In all instances, a common format and scope should be defined for the content of the release notes document and this document must accompany every software upgrade or patch.

5. Would standardizing terminology and standardizing design of control panels facilitate safe use of the equipment?

Yes, standardizing terminology and methodology would certainly help promote patient safety. FDA, the manufacturers and the users need to work together to develop a taxonomy that can be easily understood for common elements. We understand why manufacturers market their devices emphasizing differences and we believe that they care a great deal about patient safety. However, such individualization can lead to confusion and mistakes in clinical use. A balance must be achieved between appropriate marketing differences and the need for standardization. For example, it is counterproductive for manufacturers to apply special names for standard QA tests they supply or promote for their equipment.

6. Should custom-tailored educational material, such as pamphlets, pocket cards, videos etc. that highlight unique features of the equipment, be provided with new equipment?

Yes, custom-tailored educational materials should be provided. These "Quick Reference Guide" documents should utilize the standardized terminology mentioned above. Any teaching tool that helps the user understand the equipment he or she is using is welcomed. Unique features of a given piece of equipment often lead to the most confusion and require specialized training.

C. Quality Assurance Measures

1. Is there a model QA program that exists which is widely accepted? If so, please describe.

There are existing paradigms such as the AAPM TG40, TG142 and TG45 reports, with a new report nearing completion, which defines a philosophy for generating an optimum QA program for a given technology. The professional societies (AAPM, the American College of Radiology, the American Society for Radiation Oncology) are collaborating on White Papers for specific technologies such as IMRT, IGRT, SBRT, and HDR. While the existing documents describe the scope of relevant QA procedures that could be performed, they generally do not provide clear prioritization of the various QA procedures. The net result is that wide variation continues to exist across the country. A concise set of Minimum Practice Standards for QA in radiation oncology, if mandated, could significantly improve the consistency of QA programs in radiotherapy clinics across the country. If developed, such Minimum Practice Standards would be updated regularly (e.g., every 5 years) to ensure that the standards remain current.

2. What types of QA should be the responsibility of the facility, the physicist, the operator, others?

QA of the equipment and of the manner in which the equipment is used remains the responsibility of the clinic's professional team – medical physicists, therapists, dosimetrists, engineers, and the physicians. In general, the medical physicist defines the responsibilities and is responsible for ensuring that all aspects of the program are accomplished in accordance with policy and results of tests remain within tolerances for clinical use.

3. Should manufacturers provide QA procedures to medical facilities and users of radiation therapy devices? If so, why, and what instructions should be provided? If not, why not? How extensive should they be?

QA procedures should be clearly defined, with a common terminology, and with a scope of testing that is appropriate for the technology being used. The local physicist should clearly understand what the QA procedures are designed to test, and what the tolerances mean. Toward that end, an objective body of subject-matter experts should define the appropriate QA procedures. The AAPM could serve this role quite well. The manufacturers could then provide some QA tests built into their equipment, provided that the tools comply with the AAPM recommendations for the specific technology in question. Other companies producing QA devices or software should also follow the AAPM recommendations for the given technology.

4. Should manufacturers provide training on QA practices? If so, why, what type of training should be provided, and to which personnel? If not, why not and who should?

No. This should be provided through the national professional associations, with direction from medical physicists. QC procedures specific to a piece of equipment, driven by the accepted QA practices, are the appropriate realm of the manufacturer.

Food and Drug Administration Public Meeting

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

Michael G. Herman, Ph.D.

President

American Association of Physicists in Medicine

Patient Safety Device Improvements and Reporting

- We are ALL in this together!
  - Manufacturers
  - User Community
    - Physicians, Medical Physicists, Radiation Therapists, Dosimetrists, Administration
  - Regulators
    - FDA, NRC, CRCPD, …
  - United States Congress

The Medical Radiation Process Overview

Roles of Team members, Manufacturers, Regulatory agencies

key: Activity | Manufacturer | Medical Team | Regulator

At Manufacturer

Equipment/Technology Development	Product Mgr Engineers Physicist	Physicist
Equipment/Technology Manufacture	Manufacturer	Regulator

At Medical Institution
New Process/ Procedure Implementation

Concept Plan Commission Quality Control	Physician Physicist Therapist Dosimetrist

At Medical Institution
New Equipment Implementation

Selection/Purchase	Manufacturer	Medical Team	
Installation/Acceptance Test	Manufacturer	Physicist	
Commissioning & Calibrate	Regulations NRC + States for Radioactive Materials ---- X-Ray Equipment - Varies widely by State	Physicist	2nd Physicist
Establish and perform QA		Physicist	Therapist
Maintenance/Upgrades	Manufacturer	Physicist	

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	Physicist

Therapy Needed — **Surgery, Medical Oncology, Interventional Radiology/Cardiology**

Radiation Therapy

Consultation	Regulations Limited, varies widely by State Federal only NRC for materials	Physician
Simulation		Physician, Therapist Dosimetrist, Physicist
Dosimetric Planning		Physician, Dosimetrist, Physicist
Treatment Verification/QA		Therapist, Physicist Dosimetrist
Treatment Delivery		Therapist, (Physician, Physicist)
Follow Up		Physician

Enhance Medical Radiation Equipment Manufacturing Process

- Results of manufacturer risk and hazard analysis must be:
  - Submitted in the 510(k) review
  - Translated into warnings and cautions provided in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Manufacturers: provide a validation testing environment that simulates usability under expected clinical conditions (reality)
  - Clinical user community included in validation testing and use case development
  - Results submitted in the 510(k) review
  - Relevant findings published in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Manufacturer: demonstrate compliance with stated specifications and document product limitations
  - Submitted in 510(k) review
  - Provided in customer product documentation
- Provide summary of technology specific quality assurance and quality control work already performed
  - Submitted in 510(k) review
  - Provided in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Standardize key safety and operational feature nomenclature and display
  - Follow industry standards IEC/ANSI?
  - This could improve user attention.
  - Should include both planning and delivery
- Create common/consistent error message nomenclature to clearly inform user of problems

Enhance Medical Radiation Equipment Manufacturing Process

- Provide configurable stop points in process for users to employ “time out”
- Incorporate more automatic safety checks throughout the process
- Provide clear, automated, dynamic out of tolerance recognition safety features to inform user/shut off treatment.

Enhance Medical Radiation Equipment Manufacturing Process

- Mandate use of checksum for data transfer
  - Provide user with clear message if transfer fails
  - Provide user with clear information on checkpoints
- Conform to IHE-RO standards
- Provide mechanism for rapid consistency check at key points
  - e.g. simulation of treatment delivery compared to planned data at planning export and treatment delivery

Enhance Medical Radiation Equipment 510(k) Process

- Utilize external, expert, objective technical/safety reviews
- Based on more detailed safety and clinical compliance data submitted
- Costs for additional testing and external review may be offset by sales or in review process

Reporting

- Uniform, consistent, quantitative, accessible national reporting and notifications is critical
  - Single centralized repository, regardless of radiation modality, is essential for collation and data analysis – All Medical Events Together
  - Easy, universally available, anonymous event and potential event reporting
    - By users, manufacturers, others
    - Non-punitive
    - HIPAA compliant
    - Integrate some reporting tools into planning and delivery technology

Reporting

- Defined nomenclature, event definitions, minimum reporting details, used by all parties in single central repository.
  - intuitive, non-intimidating and consistent across the nation
  - requires FDA, NRC and CRCPD, others to integrate/cooperate effort.
  - User community involved.

Reporting

- Comprehensive analysis process established
  - evaluate data regularly for patterns/warnings
  - separate critical safety items from others
  - disseminate to user/manufacturer community
    - →improved process & technology
  - could be automated
- Congressman Markey's questions/responses of March 2010 following Congressional hearing (event reporting)

Summary

- Manufacturers
  - Hazard and validation test data uniformly reported in 510(k) and to users
  - Increased communication/display standardization
  - Increased robust safety checks
- FDA 510(k) process
  - Review of additional safety and testing data
  - Leverage objective external expert reviews
- Reporting System
  - Single, national, easy-to-use, accessible database
  - Standardized data entry/nomenclature
  - Evaluated for patterns and dissemination

Summary

- Work towards integrated and cooperative efforts between FDA, NRC, CRCPD, manufacturers and users
- We must all work together to bring about a lasting culture of safety
- AAPM/ACR/ASTRO – Safety Task Force
- Safety in Radiation Therapy – Call to Action June 24-25, Miami

FDA Public Meeting

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

James M. Galvin, D.Sc., FAAPM, FASTRO

Chair - Treatment Delivery Subcommittee (Therapy Physics Committee of AAPM)

A Number of Factors Impact RT Patient Safety

- Fail Safe equipment design
- Complete and effective QA procedures in place prior to equipment release
- Well documented user manual
- Qualified user trainers

User Training Must Recognize and Emphasize the Following

- Errors relating to the quality of a patient's treatment plan and catastrophic treatment failures are different
  - Examples of errors relating to plan quality are associated with factors like not strictly adhering to the prescription or poor contouring
  - Catastrophic failures and malfunctions relate to equipment/software failures and human error

User Training Must Deal with Errors, Failures and Malfunctions

- We now recognize that the two classes of problems identified in the previous slide require different solutions
  - The RTOG, working with the RPC and ITC, offers a good model for handling errors related to quality of the final delivered dose
  - Catastrophic failures and treatment unit malfunctions require some additional QA steps not included in the RTOG model

User Training Must Deal with Errors, Failures and Malfunctions

- Catastrophic failures and malfunctions require attention to the following factors:
  - Faithful transfer of data among various systems in the treatment delivery process
  - Clarity of warning messages
  - Failure modes that produce a safe result
  - Fast and complete reporting of failures

How Can FDA Determine the Effectiveness of Training?

- The AAPM recommends using testing and evaluation procedures to determine the effectiveness of each manufacturer's training process.
  - Manufacturers should provide feedback to departmental administrators regarding effectiveness of training program
  - Users should evaluate trainers and present results to manufacturers

Material Presented by User Trainers

- Functional aspects relating to operation of device
  - Including detailed error messages
- Safety aspects relating to quality assurance for device
  - Describe and demonstrate any QA devices produced by manufacturer or bundled
  - Distribute and discuss any relevant QA testing procedures from peer reviewed literature or other sources that are critical for patient safety

User Societies and Other Groups Must Help Manufacturers

- The AAPM, ASTRO and ACR are working together to develop a new QA paradigm for solving the problem of catastrophic failures in radiation oncology.
- Now is the time to engage other groups like the FDA, MITA, ASRT, IEC and the CRCPD.
- Manufacturers should be aware of the activities of the user societies in developing new QA recommendations.
- These recommendations should be incorporated in the user training process.

User's Responsibilities

- User must work with manufacturer to schedule training time that overlaps with first patient treatment
- User must guarantee availability of all critical personnel
  - therapist, physicists, dosimetrists, clinicians
- User must reschedule training for new hires when in-house training is not practical

Where Do We Go From Here?

- The AAPM will send forward a proposal to develop a guidance document relating to manufacturer user training at its upcoming meeting in Philadelphia in July

Where Do We Go From Here?

- Accountability is needed from all parties: users, manufacturers, FDA
  - Department heads and administrators need to know that personnel are able to Work Safely
  - Manufacturers need to assess the effectiveness of their training programs and improve them as needed
  - FDA needs to know that the equipment they approve for marketing is safe for patients

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

Per Halvorsen, MS, DABR, FACR

Chair, Professional Council

American Association of Physicists in Medicine

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 all 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.

Need: 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 all 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 all 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