Are You Driving the Bus, or Along for the Ride? How the Media is Influencing Your Profession

Lynne A. Fairbent
Manager of Legislative and Regulatory Affairs
American Association of Physicists in Medicine
lynne@aapm.org
ACMP
May 1, 2011

Objectives

• At the end of this, the participant will understand:
  – Understand the impact of the media on day-to-day practice
  – Understand how the media can influence the promulgation of legislation and regulation
  – Why understanding the legislative and regulatory process is importance to every day practice

How Did We Get Here?
Radiation in the News

January 22, 2001

CT scans in children linked to cancer later

[Image of a newspaper article]
Increased Media Focus

While new technology saves the lives of countless cancer patients, errors can lead to unspeakable pain and death. January 24, 2010

New York Times Articles
January 27, 2010

- THEY CHECK THE MEDICAL EQUIPMENT, BUT WHO IS CHECKING UP ON THEM? Loose regulation of medical physicists has allowed problems to enter a part of the process meant to make health care safer.

A Request You Can't Ignore
February 4, 2010

...
Increased regulation likely:

The New York Times

February 10, 2010

F.D.A. to Increase Oversight of Medical Radiation

The federal Food and Drug Administration said Tuesday that it would take steps to more strictly regulate three of the most potent forms of medical radiation, including increasingly popular CT scans, some of which deliver the radiation equivalent of a short X-ray.

With the announcement, the F.D.A. puts its regulatory muscle behind a growing movement to make life-saving medical radiation—both diagnostic and therapeutic—not.

Last week, the leading radiation oncology association called for enhanced safety measures. And a Congressional committee was set to hear testimony Wednesday on the weak oversight of medical radiation, but the hearing was canceled because of bad weather.

House of Representatives
Subcommittee on Health Hearing

• Hearing - Medical Radiation: An Overview of the Issues (originally scheduled Feb 10, 2010)
• Expert panel
• Invited organizations
  – AAPM
  – ACR
  – ASTRO
  – ASRT
  – MITA

Congressional Focus

American Association of Physicists in Medicine

Statement of Michael G. Herman, Ph.D., FAAPM, FACMP
On Behalf of the American Association of Physicists in Medicine (AAPM)
Before the Subcommittee on Energy and Commerce

February 26, 2010

Chairman Fallone, Ranking member Den and members of the distinguished committee, morning and thank you for the opportunity to testify today on Medical Issues.

It is my pleasure to be here representing the American Association of Physicists in Medicine (AAPM). AAPM is a scientific and professional organization.

AAPM Testifies Before Congress

• As many of you know, there have been a number of recent articles in the press related to tragic errors in radiation therapy. This combined with the recent publicity on CT perfusion dose problems has prompted Congress to call a hearing entitled “Medical Radiation: an Overview of the Issues”. AAPM, along with ASTRO, ACR, ASRT and MITA have been asked to testify to help guide direction for improving patient safety in the medical use of radiation. We sincerely believe that working together with all stakeholders that we can improve safety and quality in the medical use of radiation.

Mike Herman, AAPM President
AAPM Statement

• In summary, the AAPM believes that patient safety in the use of medical radiation will be increased through: consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. We must also learn from our mistakes by collecting and evaluating them at the national level. AAPM has been working directly and in cooperation with other stakeholders for years on some of these issues and we are saddened that some people are injured during what should be beneficial procedures. We believe that more effort on all seven areas of focus, by all of us, working cooperatively, will continue to make the use of medical radiation safer and more effective for the people that need it.
Increased media focus

St Louis Today: Rural Missouri

Increased funding for National Cancer Institute and the Radiological Physics Center

Congressional Hearings

- Expanding federally mandated accreditation requirements to include all clinical settings (diagnostic and therapeutic)
- Federally mandated CT dose index registry
- National database for reporting linear accelerator errors
- Enhanced adoption of electronic medical records
- Legislation to enforce patient safety
- Federal mandate for board certification of medical physicists and uniform licensing requirements
- Passage of the CARE Act, which requires minimum educational and credentialing standards for technical staff
- Rigorous minimum standards for accrediting clinical practices
- Mandatory public, anonymous reporting of radiation therapy “near misses”
- Development of radiation dose reference levels

Congressional Hearing

- Federal mandate for board certification of medical physicists and uniform licensing requirements
- Passage of the CARE Act, which requires minimum educational and credentialing standards for technical staff
- Rigorous minimum standards for accrediting clinical practices
- Mandatory public, anonymous reporting of radiation therapy “near misses”
- Development of radiation dose reference levels

March 31, 2011

Participating:
Rep. Myrick, R-NC
Rep. Capps, D-CA
National Patient Advocate Foundation
AAPM
ASRT
ASTRO
Representative Sue Myrick [R-NC-9th]

- “As a cancer survivor myself who has undergone radiation therapy, I can personally attest to the value of this cancer treatment,” Myrick said. “Radiation therapy technology has become more precise and state of the art compared to just a decade ago. It is important that cancer patients have access to this critical therapy. It allowed me to continue my normal routine while undergoing treatment. I credit my speedy recovery in large part to radiation therapy, and the caring expertise of my doctors.”

Representative Lois Capps [D-CA-23rd]

- “I applaud this community for coming together to raise awareness about the benefits of advanced radiation therapy services in cancer care,” added Capps. “As a nurse, I remain committed to working with the medical community, and my fellow lawmakers, to build on the important protections for individuals with cancer in the Affordable Care Act and protect access to potentially life-saving treatments upon which so many patients depend.”

Dr. Gary Ezzell, AAPM President-elect

“Radiation therapy has become much more complex, both in technology and procedures. We are able to better control the shape and location of the radiation dose,” added Dr. Gary Ezzell, president-elect of the American Association of Physicists in Medicine (AAPM). “AAPM supports efforts to further improve these potentially life-saving therapies for patients.”
AAPM Remarks

• Improvements in patient safety for the medical use of radiation
  – Radiation therapy has become much more complex, both in technology and procedures. We are able to better control the shape and location of the radiation dose. This is good for patients, as long as it is done well.
  – In many states, the requirements for professional training and accreditation of non-physician team members are weak or non-existent. AAPM supports the passage of the CARE bill to address this problem.

AAPM Remarks (continued)

• Improvements in patient safety for the medical use of radiation
  – AAPM also supports the concept of practice accreditation to help ensure that well-trained individuals are working together following nationally accepted guidance.
  – Errors and near-misses will still sometimes occur. AAPM is working with ASTRO and other professional organizations to develop a national event reporting system, so that we can more readily learn from each other’s experiences.

AAPM Remarks (continued)

• Improvements in patient safety for the medical use of radiation
  – AAPM supports and is working toward safety improvements in the medical device manufacturing and regulatory approval process.
  – AAPM appreciates congressional support for these safety improvements.

Congressional Offices Represented

• Senator Kent Conrad (D-ND)
  • Senator Charles Grassley (R-IA)
  • Senate HELP Committee
• Rep. John Conyers (D-MI)
• Rep. Gene Green (D-TX)
• Rep. Patrick Meehan (R-PA)
• Rep. Anna Eshoo (D-CA)
• Rep. Allyson Schwartz (D-PA)
• Rep. Jim Gerlach (R-PA)
• Rep. Steve Israel (D_NY)
• Rep. Mary Bono Mack (R-CA)
• Rep. Frank Pallone (D-NJ)
Physicians, Advocates, Lawmakers Gather on Capitol Hill to Discuss the Value of Radiation Oncology

Leaders from the radiation oncology community—representing patients, physicians, providers, and manufacturers—recently met on Capitol Hill to educate lawmakers and their staffs about the latest in radiation therapy technologies and techniques, improvements in patient care, and the community’s focus on patient safety in radiation therapy delivery. Representatives Sue Myrick (R-N.C.) and Lois Capps (D-Calif.) participated in the briefing to share their personal experiences with cancer care and underscore the importance of this vital health care tool in our nation’s continued fight against cancer.

California CT Law

- Senate Bill 1237 amended Section 11511 of the CA Health and Safety Code to mandate strict procedures and reporting requirements for CT scanners and radiation-therapy procedures to include radiation overdoses to the Department of Public Health.
  - Effective date July 2012
  - MDs must record radiation dose on the radiology report and attach the protocol to the report
  - Dose must be verified annually by a medical physicist to ensure that the displayed dose is within 20% of the measured dose
  - Reporting requirements if radiation dose is exceeds the or include the wrong area of the body
  - July 2013 all facilities that offer CT must become accredited by an organization approved by CMS
  - Because this bill expands the definition of a crime, it will impose a state-mandated local program.
California CT Law

- Law does not require
  - Quality Assurance or equipment standards
  - Training and education for operators
  - Qualification and education of Medical Physicists
  - Radiation dose tracked on a per-exam basis
  - Only concerned about individual procedures and lifetime accumulation of radiation

Information Notice Regarding Senate Bill (SB) 1237, California Health and Safety

- (H&S) Code Section 115113
- Sent to All Facilities Using X-Ray Computed Tomography (CT) Equipment
- This Q&A only applies to H&S Code Section 115113, recently enacted by SB 1237 (Padilla, Chapter 521, Statutes of 2010), which added reportable events from the use of X-ray CT and therapy. H&S Code Section 115113 became effective January 1, 2011.

American Medical Isotopes Production Act of 2011

USA Today – August 14, 2009

Medical isotope shortage threatens treatments

- Health updates on Twitter
- Latest health news from @USATODAYHealth
- Whole-grain cereal may help control blood pressure http://thestist.com/2009/08/14/whole-grain-cereal-may-help-control-blood-pressure

Some 15 million people in the United States — 40,000 patients each day — undergo procedures that require medical isotopes. In the United States, 80 percent of nuclear medicine scans use it.
American Medical Isotopes Production Act of 2011

S. 99

To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

IN THE SENATE OF THE UNITED STATES

January 5, 2011

We, your Senate, having considered the following bill, do pass the same.

A BILL

To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

PHYSICS TODAY – FEBRUARY 4, 2011

Senate committee seeks to create a US source for widely used medical isotope

A bill to create a domestic supply base for molybdenum-99, a short-lived radioactive isotope widely used for medical imaging, was reintroduced in the Senate in late January. Virtually identical to a similar measure that failed to pass in the 111th Congress, the legislation is intended to provide a domestic source of the material to ensure a continuous supply and to reduce the nation’s dependence on foreign sources.

The introduction of S.99 marks a legislative push that started last year following the death of a single isotope maker, Sonata International, Inc. (SII) of Boulder, Colorado. In November, a Senate subcommittee voted to fund $10 million in grants for a molybdenum-99 production plant, and in February, the Senate Committee on Appropriations provided an additional $10 million to fund the project.

The bill’s sponsor, Senator Bingaman (Dem-NM), signed on last year, said a Senate committee was considering what additional measures might be needed to provide a domestic source of molybdenum-99 to the US and to prevent a recurrence of the shortage that led the one isotope maker to close its doors.

Credentials of Imaging and Radiation Therapy Personnel
X-Rays and Unshielded Infants

It was well after midnight when Dr. Salvatore J. A. Scifers finally hit the "send" button.

Some colleagues would awake to his e-mail, expressing his anguish and shame over the discovery that the tiniest, most vulnerable of all patients — premature babies — had been over-exposed in the department he ran at State University of New York Downstate Medical Center in Brooklyn.

A day earlier, Dr. Scifers noticed that a newborn had been irradiated from head to toe — with a metal shield blocking — even though only a single chest X-ray had been ordered.

"I was mortified," he wrote on July 27, 2007. Worse, technologists had given the same baby about 10 of those whole-body X-rays. "Full, unshielded, total irradiation of a neonate," Dr. Scifers wrote in an e-mail to New York State Department of Health.

The errors at Downstate raise broader questions about the competence, training and oversight of technologists who operate radiological equipment that is becoming increasingly complex and powerful.

If technologists could not properly take a simple chest X-ray, how can they be expected to safely operate CT scanners or linear accelerators?

With technologists in many states lightly regulated, or not at all, their own professional group is calling for greater oversight and standards. For 12 years, the American Society of Radiologic Technologists has lobbied Congress to pass a bill that would establish minimum educational and certification requirements, not only for technologists, but also for medical physicists and people in 10 other occupations in medical imaging and radiation therapy.

AAPM Responds to New York Times

The American Association of Physicists in Medicine (AAPM) is a scientific and professional organization composed of physicists (medical physicists) whose clinical practice is dedicated to accuracy, safety and quality in radiation oncology, medical imaging, image-guided medical procedures, and medical radiation safety. Articles published recently in the New York Times have focused on rare events in radiation therapy and imaging that have resulted in tragic consequences for patients. The AAPM and its members deeply regret that these events have occurred, and are committed to actions to prevent their recurrence.

The American Association of Physicists in Medicine (AAPM) believes that one way to address concerns about healthcare quality, radiation safety and safe equipment operation is to enact legislation that would establish minimum education, training, and experience requirements for all individuals involved in imaging and radiation therapy. "We look forward to working with the AAPM in this endeavor," said AAPM President Alistair Bainbridge.

For the past 12 years, the AAPM along with the other members of the Alliance for Quality Imaging and Radiation Therapy have lobbied Congress to pass a bill that would establish minimum educational and certification requirements, not only for medical physicists, but also for technologists and others in 15 other occupations in medical imaging and radiation therapy:  

"Protecting patients in medical imaging and radiation therapy: Responsibility and excellence in medical imaging and radiation therapy," is a method to improve patient safety.
AAPM Responds to New York Times

- In summary, AAPM believes that patient safety in the use of medical radiation will be increased through:
  - 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.

CARE Bill and the 112th Congress

- CARE stands for: Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2011
- Anticipate introduction by end of May
- Draft Bill text is similar to the S. 3737
- Does not include exemption for MIPPA Advanced Imaging Modalities

Safety Culture Policy

- Commission directed staff to expand safety culture policy to all licensees
- Initial statement published January 23, 2009 (74 FR 4260)
- Revised statement published September 17, 2010 (75 FR 57081)
- Commission Approved Publication of Safety Culture Policy March 7, 2011
- Final Federal Register Notice in Process

Draft Safety Culture Policy Statement
Revised Definition of Nuclear Safety Culture

• “Nuclear Safety Culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.”

Purpose of this Statement of Policy

• Is to set forth the Nuclear Regulatory Commission’s expectation that individuals and organizations, performing or overseeing regulated activities involving nuclear materials, establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions.

Patient Release Rule Issues
NRC’s Patient Release Rule

- Questions 10 CFR § 35.75
- In 2005 Peter Crane filed a Petition for Rulemaking questioning the regulation
- Most in the medical community requested NRC deny the Petition
- NRC denied the Petition but this did not end Mr. Cane’s concerns

Rep. Markey – Patient Release
Patient Release Public Dose Limits – Per Annum v. Per Episode

- NRC’s current regulations are silent on the issue of per annum v. per episode
- RIS-08-07 (March 2008) states: “NRC intends to pursue rulemaking to clarify the 5 mSv (0.5 rem) limit in 10 CFR § 35.75 as an annual, rather than a per episode release limit”
- The Statements of Consideration support the NRC determination that the regulation as it is currently written intended an annual dose limit based on the presumption appropriate at the time the regulation was developed

Patient Release Public Dose Limits – Per Annum v. Per Episode - continued

- January 5, 2011 ACMUI recommended that NRC pursue rulemaking to clarify the criteria, and endorsed a per episode limit.
- April 11, 2011 confirmed the January 5th recommendation and stated that they do not recommend any change to the regulation and does not recommend the NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit.

DR. OZ AND THYROID GUARDS
First aired September 2010

- Thyroid cancer is 4 times more common in women than men, so the finger naturally points to estrogen
- Interestingly, the increase in thyroid cancer also began to rise just as X-ray radiation was being routinely used to diagnose and treat disease. This was a time when X-rays were not only stronger, but also used indiscriminately for some unworthy conditions such as acne and tonsillitis.
- The thyroid gland however, is very sensitive to radiation; it is a leading risk factor for the condition, especially if exposure occurred during childhood.

Dr. Oz’ Comments

- And although routine dental X-rays, chest X-rays and mammograms of today use much lower and safer amounts of radiation, some worry about this as a thyroid-damaging source. Some professionals say to protect the thyroid people should wear a lead thyroid shield (and apron when possible) when undergoing these procedures block radiation reaching the thyroid gland, and to limit tests using X-rays to those that are absolutely necessary. Other risk factors for thyroid cancer include hereditary conditions and iodine deficiency (rare in the US because of iodized salts).
Viral Email: Precautions re: Mammograms and Dental X-Rays/ A Useful Warning

On Wednesday, Dr. Oz had a show on the fastest growing cancer in women, thyroid cancer. It was a very interesting program and he mentioned that the increase could possibly be related to the use of dental x-rays and mammograms. He demonstrated that on the apron the dentist puts on you for your dental x-rays there is a little flap that can be lifted up and wrapped around your neck. Many dentists don't bother to use it. Also, there is something called a "thyroid guard" for use during mammograms. By coincidence, I had my yearly mammogram yesterday. I felt a little silly, but I asked about the guard and sure enough, the technician had one in a drawer. I asked why it wasn't routinely used. Answer: "I don't know. You have to ask for it."

Well, if I hadn't seen the show, how would I have known to ask?

Someone was nice enough to forward this to me. I hope you pass this on to your friends and family.

Professional Societies React

The ACR and Society of Breast Imaging Statement on Radiation Exposed to the Thyroid from Mammograms

April 1, 2011

Some Americans have expressed concern, date to a report crediting that the small amount of radiation to a a thyroid gland has mammogram may significantly increase the likelihood of developing thyroid cancer. This concern simply is not supported in scientific evidence.

The radiation dose to the thyroid from a mammogram is extremely low. The thyroid is not exposed to the x-ray beam to any extent. Thus, there is no evidence that mammograms cause thyroid cancer. This is supported by over 30 years of federal regulation of radiation exposure for all Americans from natural sources.

For annual screening mammography (using x-rays), the cancer risk from the tiny amount of radiation is estimated to be a 1 in 1000 or 0.1%. The overall risk is 1 in 100 for women over 20 years of age. The risk can be further reduced by avoiding mammograms when the whole body is exposed to radiation.

AAPM Response to Dr. Oz Show

In guidance to medical professionals, the AAPM also cautions that thyroid shields can obscure mammography results to the point that otherwise unnecessary follow up tests are required. As stated:

"The use of thyroid shields during mammography exams is unsupported by the scientific literature, and could result in unnecessary increases in breast dose due to repeated mammography exams. Thus the use of thyroid shields is strongly discouraged. The use of lap shields is voluntary and is only recommended in women who are or may be pregnant at the time of the exam."


Dr. Oz - "Thyroid Shield Controversy"

In response to the Joint ACR/SBI Statement issued, the Dr. Oz show aired a rebuttal show last week. The show aired Thursday, April 14, 2011. With Breast Imaging experts Daniel Kopans, MD - ACR, W. Phil Evans, MD - SBI, Jocelyn Rapelyea, MD - George Washington University

ASRT Responds

News Release

Thyroid Shield Not Recommended During Mammograms

Mammographers have reported to ASRT that a growing number of patients are requesting a thyroid shield be used during their mammography examinations. The requests are the result of advice originally given on a television show last year and repeated in an e-mail message that has circulated to thousands of doctors and nurses in the past few weeks. The doctors are finding that a small number of patients have been told that thyroid damage could result from mammography examination and are requesting thyroid shields during mammography examination to avoid investing in or developing thyroid cancer.

Although every institution has its own mammography protocols, the ASRT does not recommend the regular use of a thyroid shield during mammography exams. "We acknowledge that mammography and radiation therapy share the same or similar equipment and settings and are therefore exposed to the same or similar radiation risks. However, the vast majority of mammography patients are not prone to radiation exposure associated with treatment of breast cancer. The vast majority of mammography patients are not irradiated in the same way that a breast cancer patient is. The American College of Radiology and Society of Breast Imaging have provided information about the estimated radiation dose to the thyroid that may be incurred in screening your patients' breasts. Mammographers can also explain that using a thyroid shield might interfere with the accuracy and quality of the examination.

In addition, mammographers can direct patients to the ASRT-sponsored site www.asrt.org to learn more about radiation exposure and to view their medical Imaging history. Patients can also learn about the risks and benefits of imaging procedures at the Image Library website: www.imagelibrary.org.

VA Brachytherapy Incident Example

NRC Proposed Rule on Medical Events from Brachytherapy

• RIN 3150-A126 draft rule language for proposed changes to 10 CFR §35.40 and §35.3045 related to medical events in brachytherapy. The first notification of the proposed changes was issued February 7, 2008 and revision 1 February 21, 2008.

• Proposed Rule for Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150-A126, NRC-2008-0071) [See 73 FR 46635 (August 6, 2008) and 73 FR 58063 (October 6, 2008)]

NY Times Article – At V.A. Hospital, a Rogue Cancer Unit – June 21, 2009

At V.A. Hospital, a Rogue Cancer Unit

Dr. Sam Koo, a radiologist at the Veterans Administration hospital in Philadelphia, gave his patient a too-high dose of radiation in 2005. The patient, who had cancer, died. Years later, Dr. Koo was disciplined but not fired.

But when the VA said that Dr. Koo had ordered the too-high dose, the hospital said he had ordered the too-low dose. A medical examiner said Dr. Koo had ordered the too-high dose to begin with.

A medical examiner said Dr. Koo had ordered the too-high dose to begin with. The VA has conceded that Dr. Koo was right, but the hospital has refused to change its report on the death.

The VA has conceded that Dr. Koo was right, but the hospital has refused to change its report on the death. But the VA has conceded that Dr. Koo was right, but the hospital has refused to change its report on the death.
Recent NY Times Articles

- V.A. IS FINED OVER ERRORS IN RADIATION AT HOSPITAL
  The Nuclear Regulatory Commission cited an "unprecedented number" of mistakes by the Philadelphia Veterans Affairs Medical Center in treating prostate cancer patients. March 17, 2010.

NRC Fines VA - $227,500

Fine against VA Hospital Is Second Largest in NRC History

According to a story published on 5/17/10 in the New York Times, the hospital was fined $227,500 after the Nuclear Regulatory Commission (NRC) found violations during a review of the hospital's radiation treatment program. The hospital was cited for allowing patients to be exposed to radiation doses that were too high, resulting in unnecessary treatment and increased risk of cancer.

The NRC regulates the use of radiation in medical treatment. The commission's rules require hospitals to ensure that patients are exposed to the minimum amount of radiation necessary to achieve the desired therapeutic effect. The violation occurred at the Philadelphia VA Medical Center, where the NRC found that the hospital had allowed patients to be exposed to radiation doses that were too high, resulting in unnecessary treatment and increased risk of cancer.

Medical errors at VA hospitals have been a significant concern in recent years, and the NRC's decision to fine the Philadelphia VA Medical Center reflects the agency's commitment to enforcing its rules and ensuring that patients are treated safely.

Philadelphia VA Medical Center's Unprecedented Radiation Errors

The Nuclear Regulatory Commission (NRC) cited the Philadelphia VA Medical Center in a recent inspection for "unprecedented number" of mistakes in radiation treatment, resulting in a $227,500 fine.

The NRC found violations during a review of the hospital's radiation treatment program, with the agency citing multiple instances of patients being exposed to radiation doses that were too high. The violations were considered serious enough to warrant a significant fine.

The Philadelphia VA Medical Center is one of the largest VA hospitals in the country, providing care to veterans across the region. The hospital has been the subject of criticism in recent years, with reports indicating that veterans have experienced delays in access to care and other issues with quality of care.

The NRC's decision to fine the Philadelphia VA Medical Center reflects the agency's commitment to enforcing its rules and ensuring that patients are treated safely. The fine is one of the largest ever imposed by the NRC, and the agency is expected to continue its efforts to address issues related to radiation safety at VA hospitals.
NRC Issues Orders to Two Individuals Involved in 2002-2008 Medical Errors at VA Medical Center in Philadelphia

The Nuclear Regulatory Commission has issued an order that bars a former Veterans Administration (VA) physician from engaging in NRC-regulated activities unless he undergoes certain testing and meets other requirements spelled out by the agency. The order involving Dr. Gary Kao, who previously worked at the Veterans Affairs Medical Center in Philadelphia (VA Philadelphia), takes effect 30 days after its issuance.

At the same time, the NRC has issued a separate order requiring a medical physicist who worked at the same facility to notify the agency if he accepts employment in a capacity involving NRC-regulated activities. Gregory Chengney must carry out such notification within 20 days of beginning such work.

The orders are the latest actions taken by the NRC in response to an unprecedented number of medical errors identified at VA Philadelphia. The errors involved the incorrect placement of iodine-125 seeds in patients to treat prostate cancer. Out of 116 such brachytherapy procedures performed at the facility between 2002 and 2008, the VA reported that 77 were carried out incorrectly. On March 17, the NRC issued a $27,500 fine against the Department of Veterans Affairs for violations of agency regulations associated with the errors.

NRC STAFF’S ISSUE

- How do we appropriately balance between the medical community’s desire to define a medical event in terms of clinical significance with the interest in mistakes need to have mistakes in the have to need “NRC’s NRC process reported, even if there is no actual negative consequence to the patient?

NRC Proposed Rule on Medical Events from Brachytherapy

- Rule initially proposed August 6, 2008
- Large number of medical events reported in Summer-Fall of 2008 caused re-evaluation of the proposed rule (VA incident happened)
- Commission put proposed rule on hold until investigation was over
- Revised proposed rule based on VA investigation
- Request to NRC Commission to issue reproposed rule – SECY-10-0062 May 18, 2010
- Commission disapproved publication of reproposed rule and directed staff to work with ACMUI and stakeholders on new proposed language – August 10, 2010
- ACMUI met April 11, 2011 to discuss this issue

ASTRO recommends that the written directive refer to the total source strength implanted after administration, but before the patient leaves the post-treatment recovery area rather than an arbitrary pre-implantation written directive.
ACMUI Recommendation

- At the April 11, 2011 meeting the ACMUI recommended:
  - Permanent Implant Brachytherapy Rulemaking, the ACMUI endorses ASTRO’s approach to Permanent Implant Brachytherapy as the most appropriate approach for patient welfare. The ACMUI recommended that the NRC require Post-Implant dosimetry following brachytherapy treatment. The ACMUI also believes that prostate brachytherapy is a unique subset of brachytherapy and should therefore require a separate set of rules from non-prostate brachytherapy. The recommendation passed unanimously with eleven favorable votes.

10 CFR Part 35 Expanded Rulemaking

- Since the issuance of the revised rule in 2005, there have been a number of items identified that need clarification or amendment
  - A total of 28 specific items/issues have been identified
    - Many fall in four topic areas
  - Link to the List of specific items:

Background Part 35 Rulemaking

- Revised in its entirety in 2002
- Training and Experience regulations in 2005
- Three additional rulemaking in 2007 and 2009

Part 35 Expanded Rulemaking

- Revised in its entirety in 2002
- Training and Experience regulations in 2005
- Three additional rulemaking in 2007 and 2009
Part 35 Expanded Rulemaking

- Main issues to be discussed:
  - Medical Event Definition for Permanent Implant Brachytherapy
  - The Ritenour Petition
  - Patient Release – 10 CFR § 35.75
  - Frequency of Molybdenum-99m testing
  - Naming Associate Radiation Safety Officers (RSOs) on a medical use license

Upcoming NRC Public Workshops on 10 CFR Part 35

- NRC will hold two public workshops to discuss potential amendments to 10 CFR Part 35
- June 20 – 21, 2011 at the Flatotel Hotel, New York City
- Looking at week of August 8, 2011 in Houston, TX
- Federal Register notice has not been issued yet
- Will be a facilitated roundtable format – AAPM has been asked to participate

The Ritenour Petition Recap

- 2005 T&E regulations have inadvertently affected a group of board certified professional
- These individuals must now apply through the "alternate" pathway
- Alternate pathway places an undue burden and could result in a shortage of AMPs and RSOs

Ritenour Petition Resolution (PRM-35-20)

- NRC resolved the petition in May 2008 and concluded that 2005 revision may have adversely affected some board-certified professional, including authorized users.
- Issues raised in the petition will be considered for rulemaking if a technical basis can be developed.
Technical Basis Development

- In October 2008, NRC staff asked certifying boards to survey their Diplomates who are or may be affected by the 2005 T&E revision
- Responses were received from 5 of the 9 contacted boards
- Approximately 10,000 individuals may be potentially affected

Survey Result: Response Rate

- ABHP 44%
- ABMP 90%
- ABR
  - Radiologists 36%
  - Oncologists 42%
  - Physicists 52%
- AOBR (American Osteopathic Board of Radiology)
  - Radiologists 47%
  - Oncologists 50%

Individuals Potentially Affected

- ABHP 848
- ABMP 148
- ABR
  - Radiologists 7,900
  - Oncologists 260
  - Physicists 415
- AOBR (American Osteopathic Board of Radiology)
  - Radiologists 77
  - Oncologists 0

Boards That Did Not Respond

- American Board of Nuclear Medicine
- American Board of Science in Nuclear Medicine
- American Osteopathic Board of Nuclear Medicine
- Board of Pharmaceutical Specialties
Current T&E Attestations

- Requires each individual have a written attestation, signed by a preceptor authorized ..., that the individual has satisfactorily completed the board or alternate pathway T&E requirements in ..., and achieved a level of competency sufficient to function independently as an authorized ....

April 29, 2008 ACMUI Meeting

- Does each individual have to have a written attestation?
- Does each attestation have to be signed by a preceptor authorized individual?
- Does each attestation have to attest that the individual has achieved a level of competency sufficient to function independently as an authorized ...?

Commission Direction

- SRM M080429, May 15, 2008: Coordinate with ACMUI and Agreement States to amend preceptor requirements in 10 CFR Part 35
- SECY-08-0179, November 20, 2008: Recommendations on amending preceptor attestation requirements
- SRM SECY-08-0179: January 16, 2009: Approved recommendations.

Conceptually . . .

- Eliminate written attestation for board certification pathway
- Revise the attestation to say . . . Has demonstrated the ability to function independently to fulfill the radiation safety related duties required by the license
- Residency program directors can sign attestations if …
Discussion

- Comment on the conceptual direction
- Potential Rulemaking Challenges
  - Unintended consequences
  - The certification program may not adequately cover NRC’s regulated modalities
  - Perceived relaxation of safety requirements?

In the Part 35 expanded rulemaking, removal of the attestation requirement for board certified individuals is under consideration.

However, the NRC staff proposes to maintain the attestation requirements for “grandfathered” individuals.

April 11, 2011 ACMUI Recommendations

- Eliminate the written attestation for board certification pathway, regardless of date of certification.
- The attestation to be revised to say “has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee.”
- Supports the statement that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an authorized user (AU) in the same category as that designated by the applicant seeking authorized status, and that AU did not disagree with the approval.

Medicare News
MEDICARE NEWS - April 6, 2011

- Hospital Compare website offers new data about hospital acquired conditions at more than 4,700 hospitals across the nation - [www.HealthCare.gov/compare](http://www.HealthCare.gov/compare)

- For the first time, Medicare patients can see how often hospitals report serious conditions that develop during an inpatient hospital stay and possibly harm patients with important new data about the safety of care available in America's hospitals added today to the Centers for Medicare & Medicaid Services' (CMS) Hospital Compare website.

- "Any potentially preventable complication of care is unacceptable," said CMS Administrator Donald Berwick, MD. "We at CMS are working together with the hospital and consumer community to bring hospital acquired conditions into the forefront and do all we can to eliminate harm from the very healthcare system intended to heal us."

- CMS has gathered Hospital Acquired Conditions (HACs) rates from hospitals since 2007. Since 2008, Medicare has not provided additional reimbursement for cases in which one of the HACs was reported as having developed through the course of a patient’s hospital stay.

MEDICARE NEWS - April 6, 2011

Today's data release shows the number of times a Hospital Acquired Condition occurred for Medicare fee-for-service patients between October 2008 and June 2010. The numbers are reported as number of HACs per 1,000 discharges, and are not adjusted for hospitals' patient populations or case-mix.

Outpatients with low back pain who had an MRI without trying recommended treatments first, such as physical therapy.

The rates displayed in this graph are from data reported for discharges January 2008 through December 2008.

Outpatients with low back pain who had an MRI without trying recommended treatments first, such as physical therapy. (If a number is high, it may mean the facility is doing too many unnecessary MRIs for low back pain.)

(If a number is high, it may mean the facility is doing too many unnecessary MRIs for low back pain.)
Outpatients with low back pain who had an MRI without trying recommended treatments first, such as physical therapy.

- What does this measure tell you about a hospital's use of MRIs for low back pain?
- Although MRIs can be helpful for diagnosing low back pain, MRIs can be used too much.
- Usually, low back pain improves or goes away within six weeks and an MRI is not needed.

What are the risks of having an MRI?

- Since MRIs use magnets rather than x-rays, there is no radiation risk. However, because the magnets attract some kinds of metal, it's important for the technician to know if there are any metal objects or implants inside the patient's body, such as pacemakers, artificial joints, screws, stents, plates, or staples. Metal objects can pose serious risk to the patient and interfere with the test.
- For some MRIs, a substance called "contrast" is injected before the test to make parts of the body stand out more clearly on the images. Risks of contrast include possible harm to the kidneys or allergic reactions. Contrast shouldn't be used if it isn't needed.
- Having the test can be stressful for some people. Patients must hold still for about 15 to 45 minutes while lying on a table that moves inside a large scanning machine. While images are being taken, the machine makes loud noises.

Outpatients with low back pain who had an MRI without trying recommended treatments first, such as physical therapy.

- Standards of care say that most patients with low back pain should start with treatment such as physical therapy or chiropractic care, and have an MRI only if the treatment doesn't help.
- Finding out whether treatment helps before having an MRI is better and safer for most patients because it avoids the stress, risk, and cost of doing MRIs that patients don't need.
- If a number is high, it may mean that the facility is doing unnecessary MRIs for low back pain. For some patients with certain conditions, getting an MRI right away is appropriate care. Patients with these conditions are not included in this measure.

Outpatient CT scans of the abdomen that were "combination" (double) scans.
What does this measure tell you about the hospital imaging facility’s use of CT scans of the abdomen?

- Combination scans involve additional radiation exposure and risks associated with use of contrast.
- For this measure, if a number is very close to 1, it may mean that the facility is routinely giving patients combination CT scans of the abdomen when a single scan is all they need.
- Giving patients two scans when they only need one needlessly doubles their exposure to radiation:
  - Radiation exposure from a single CT scan of the abdomen is about 11 times higher than for an ordinary x-ray of the abdomen.
  - For a combination CT scan, radiation exposure is 22 times higher than for an x-ray of the abdomen because the patient is given two scans.
- Risks of injected contrast include possible harm to the kidneys or allergic reactions. Contrast shouldn’t be used if it isn’t needed.

Inspector’s Credentials

Do you verify the credentials of individuals from the state or federal agency when they are at your facility? If not, you might want to do so. On April 6, 2010, the State of Texas sent a letter to Industrial Radiographer Radiation Safety Officers informing them that there have been two separate, yet similar, incidents involving unidentified persons posing as radioactive materials inspectors working for the State of Texas. In both instances, the licensees stated that the individuals impersonating state inspectors approached radiography crews and attempted to conduct inspections of the crew’s operations. Based on the specific questions asked of the radiographers, it appears that the impersonator(s) have knowledge and familiarity with industrial radiography.

Checking Inspector’s Credentials

- Remember, you have the right to have the right to ask for proof of the inspector’s credentials. As a minimum, all Federal and State inspectors carry documentation complete with a photograph, physical description, and signature.
- If you are unfamiliar with someone who claims to be acting for an Agency, you should ask to see this credentialing document. You should not accept any other form of identification from someone claiming to be an Agency inspector. You can also call the office to verify the inspector’s identity.
So Has There Been Progress with Educating the Media?

Bogdanich – Hazards of Radiation (Webcast)  
April 14, 2011

- Radiation therapy can be vital to treating cancer, but the machinery and the people who operate are far from infallible. Learn what you and your family need to know.
- $65.00 – registration fee

Bogdanich’s Comments Regarding Medical Physicists

- Stated:
  - He began the investigation because he did not know much about medical radiation.
- Discovered:
  - That he discovered there are no reporting requirements for reporting medical errors and no national registry.

Most important points he made were:

- Medical physicists were some of the most valuable individuals that he came across and did not know they existed before he did these stories,
- That medical physicists play critical roles in the safe delivery of radiation,
- That we want them to be certified by states and there is a bill in Congress that has been debated for ten years and despite bipartisan support the bill has not been passed,
- That medical physicists in some ways are the patient advocate, in some ways they have to stand up and say let’s slow down and reevaluate what is being done
- Also mentioned that it was important to ask if your facility was ACR accredited.
• "We live in a society bloated with data but starved for wisdom." -Elizabeth Lindsey