Toward Minimum Practice Standards in Clinical Medical Physics:

Response to an increasing focus on reducing medical errors and validating professional competence

Per Halvorsen, MS, DABR, FACR, FAAPM
March 2012

Outline

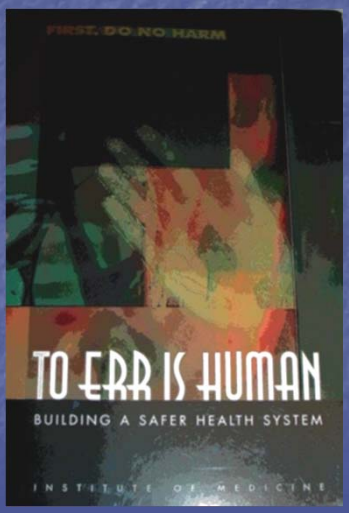
- The national (and international) focus on medical errors and quality in health care
- Federal legislative initiatives
- State regulatory changes / legislation
- Private insurance companies
- Professional society initiatives including AAPM
- Where do we go from here?

The national/international focus

- Past 2 decades → focus on medical errors and healthcare quality (adverse incidents, studies by US and European government-supported groups).
- Result: increased concern with verifying the quality of healthcare delivery and healthcare professionals' competence.

The Institute of Medicine

- In 2000, the NAS-sponsored Institute of Medicine published its first book in a series on healthcare quality, titled "To err is human".



The Institute of Medicine

- Concluded that ≈98,000 patients die each year as a result of medical errors.
- Two key recommendations:
  1. Standardize procedures
  2. Regularly validate professional competence.

The Institute of Medicine Report

"Recommendation 7.2:

Performance standards and expectations for health professionals should focus greater attention on patient safety.

Health professional licensing bodies should:

(1) Implement periodic reexamination and relicensing of doctors, nurses and other key providers, based on both competence and knowledge of safety procedures, and

(2) Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action."

Technology = Safety ??

IRSN

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

25 January 2008 / Paris

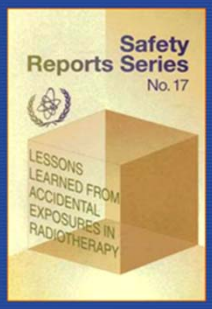
Sylvie Derreumaux, IRSN

→ Not necessarily – most failures are human process problems

The IAEA

Part 3: Analysis of causes and contributing factors

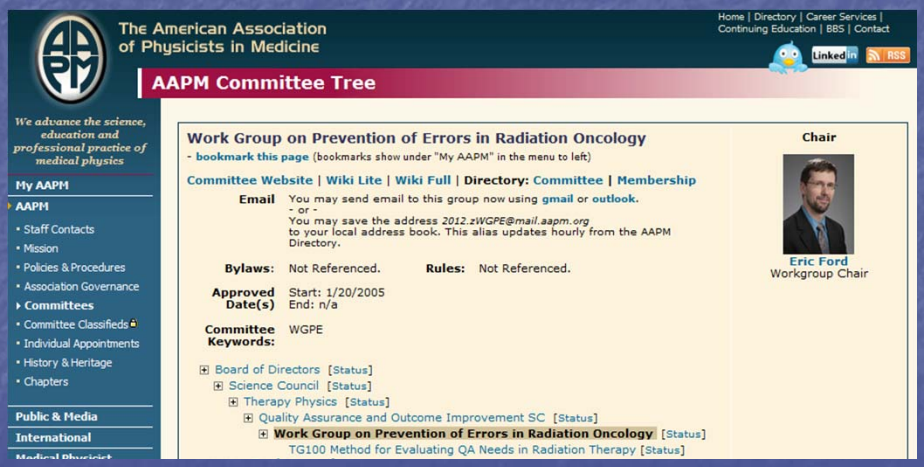
- Analysis of a collection of other incidents and accidental exposures
- The role of "near misses"
- Are there recurring themes or patterns in the "lessons learned"?



IAEA

Prevention of accidental exposure in radiotherapy 4

Errors & the AAPM



Increased media focus

Increased media focus

Scott Jerome-Parks

The Fatal Error: March 14

March 16, 2005
Mr. Jerome-Parks's medical physicist ran a series of tests on the equipment. All of them showed that the collimator was wide open, and the hospital realized that a serious overdose of radiation had been administered.

February 2007
After two years of declining health, including loss of sight, hearing and balance, Mr. Jerome-Parks, 43, died of his radiation injuries.

Increased media focus

THE PLATFORM

03.05.2010 7:44 am

Inadequate regulation puts patients at risk

By Editorial Board

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It's the kind of thing that never should happen but did. Seventy-six patients treated for head and neck tumors. On average, they got 50 percent more radiation than had been prescribed. The problems at [redacted] began in 2004 and continued unnoticed until September. Sophisticated equipment There was no independent check of the calibration, and no state or federal regulation requires it. And there ar who administer the treatment to be certified.

That certification is an option instead of a requirement "is really silly," said Dr. Eric Klein, a professor of radiatic

St Louis Today:

Rural Missouri

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 Health of the House
Committee on Energy and Commerce
February 26, 2010

Chairman Pallone, Ranking member Deal and members of this distinguished
morning and thank you for the opportunity to testify today on Medical Radia
Issues.

It is my pleasure to be here representing the American Association of Physic
generally as the AAPM. AAPM is a scientific and professional organization

CT perfusion

CT brain perfusion overexposures

The Center for Devices and Radiological Health (CDRH) issued an alert in regards to high dose levels used in head CT perfusion studies at a hospital in Southern California(1). Over 200 patients apparently received excess radiation during these time-lapse (repeated) CT studies of the head. Subsequently, similar incidents have been identified at two other hospitals in Southern California and potentially in other locations as well. Early investigations of these incidents revealed a misunderstanding of some of the automated dose selection features on the scanner, and this led to an estimated 8 fold increase in radiation to the patient. This was discovered when a number of the patients experienced some temporary hair loss (epilation) and skin reddening (erythema).

This incident apparently resulted from a lack of adequate training of CT technologists, and perhaps an overreliance on the use of preselected CT protocols. There is no

Brachytherapy

SRS

December 28, 2010

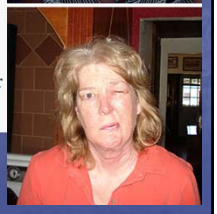
A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA REBELO

The initial accident report offered few details, except to say that an unidentified hospital had administered radiation overdoses to three patients during identical medical procedures.

It was not until many months later that the full import of what had happened in the hospital last year began to surface in urgent nationwide warnings, which advised doctors to be extra vigilant when using a particular device that delivers high-intensity, pinpoint radiation to vulnerable parts of the body.

Marci Faber was one of the three patients. She had gone to Evanston Hospital in Illinois seeking treatment for pain emanating from a nerve deep inside her head. Today, she is in a nursing home, nearly comatose, unable to speak, eat or walk, leaving her husband to care for their three young daughters.



Increased device regulation likely:

February 10, 2010

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

By WALT BOGDANICH and REBECCA R. RUIZ

The federal Food and Drug Administration said Tuesday that it would take steps to more stringently regulate three of the most potent forms of medical radiation, including increasingly popular CT scans, some of which deliver the radiation equivalent of 400 chest X-rays.

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 — safer.

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.

Learning from errors:

- Most are process failures:

ICRP Publication 86

Table 3. Classes and frequencies of accidental exposure in radiotherapy

Accidental exposures in external beam therapy	No. of cases	Percentage of cases (rounded)
Equipment problems	3	6.5
Maintenance	3	6.5
Calibration of the beams	14	30
Treatment planning and dose calculation	13	28
Simulation	4	9
Treatment set-up and delivery	9	20 (**)
Total	46 (*)	100

Federal legislation

- CARE bill: Current House and Senate versions are identical – progress being made toward passage in this session.
- Charges the Secretary of HHS to implement regulations to enforce a minimum standard for clinical professionals in imaging and radiotherapy
- The draft regulations follow the AAPM definition of QMP

CARE bill

"SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION THERAPY.

"(a) ESTABLISHMENT OF STANDARDS.—

"(1) IN GENERAL.—The Secretary, in consultation with recognized experts in the technical provision of medical imaging and radiation therapy services, shall establish standards to ensure the safety and accuracy of medical imaging studies and radiation therapy treatments. Such standards shall pertain to the personnel who perform, plan, evaluate, or verify patient dose for medical imaging studies and radiation therapy procedures and not to the equipment used.

CARE bill

"(3) REGULATIONS FOR DELIVERY OF OR PAYMENT FOR SERVICES.—Not later than 36 months after the date of enactment of this section, the Secretary shall promulgate the regulations described in subsection (h). The Secretary may withhold the provision of Federal assistance as provided for in subsection (h) beginning on the date that is 48 months after the date of enactment of this section.

The CARE bill will:

- Recognize state licensure standards that meet or exceed the federal standard.
- Require HHS to examine each state's existing program to ensure it meets the federal standard.
- Direct HHS to ensure that no later than 3 years after the date of enactment of the legislation, all programs under HHS jurisdiction adhere to the standards including payment for medical imaging or radiation therapy procedures.

MIPPA

- Medicare Improvements for Patients and Providers Act of 2008:
  - Signed into law in July 2008
  - Requires practice accreditation for the "advanced imaging" modalities which includes CT, MR, and Nuclear Medicine
  - Does not include x-ray, fluoroscopy, sonography, or anything in radiation oncology
  - Does not apply to hospitals

Accrediting bodies under MIPPA:

- American College of Radiology
- Intersocietal Accreditation Commission
- The Joint Commission
- *The Problem/Concern*
  - All have different requirements for personnel - AAPM is on record indicating concern with not requiring board certification for medical physicists

Possible national solution:

- US Congress follows MIPPA's or MQSA's lead and requires accreditation for all imaging and radiation therapy services in order to receive federal dollars (MediCare).
- ASTRO, ACR and AAPM have committed to strengthening accreditation programs

ASTRO's position:

Launching a significantly enhanced practice accreditation program and beginning the development of additional accreditation modules specifically addressing new, advanced technologies such as IMRT, SBRT and brachytherapy.

ACR's position:

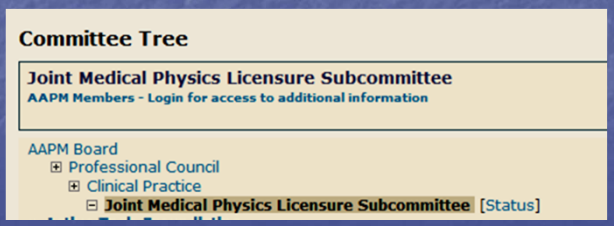
The ACR believes Congress should expand the current MIPPA accreditation requirements for advanced imaging to include radiation therapy. In addition, the accreditation mandate should apply to all facilities, including hospital settings. Furthermore, the accrediting of these imaging and radiation therapy procedures should only be conducted by those accrediting bodies with experience and expertise in the area for which they are accrediting.

State regulations

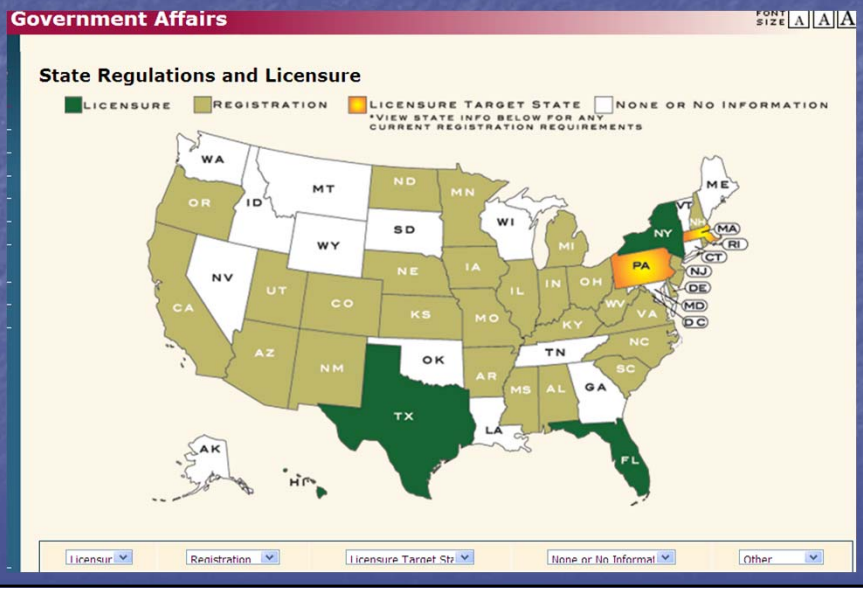
- Professional Licensure or registry.
- More states are implementing strong definitions of a QMP, with Board certification the only pathway.
- CRCPD SSRs incorporate QMP definition

Licensure & the AAPM

- Subcommittee formed to promote minimum practice guidelines through licensure or registration regulations.
- The AAPM Board has approved significant funding to support this effort (new staff member, IT support, lobbying).



State regulations



Registration

- 20 states, with more drafting new regs.
- Many follow AAPM QMP definition.
- Wide variation in professional standards and enforcement

MA Registry

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.433: continued

(C) Training for External Beam Radiation Therapy Authorized Users The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the authorized user to be a physician who is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or,
(2) Radiation oncology by the American Osteopathic Board of Radiology; or,
(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or,
(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.

(D) Training for Qualified Medical Physicist for Radiation Therapy. The registrant for any ~~therapeutic radiation machine subject to 105 CMR 120.436 or 120.437~~ shall require the Qualified Medical Physicist to:

(1) Be registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys of ~~external beam radiation therapy units; and,~~
(2) Be certified by the American Board of Radiology in:
  (a) Therapeutic radiological physics; or
  (b) Roentgen-ray and gamma-ray physics; or
  (c) X-ray and radium physics; or
  (d) Radiological physics; or,
(3) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or,
(4) Be certified by the Canadian College of Medical Physics.

Accreditation: State laws

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

EXTERNAL BEAM & BRACHYTHERAPY
QUALITY ASSURANCE PROGRAM AUDIT FORM

Purpose: To provide licensees and registrants with a standard form for documenting compliance with the audit requirements contained in 10 NYCRR 16, Section 16.24.

Background: The New York State Sanitary Code, Chapter I, Part 16, Ionizing Radiation, requires New York State Department of Health Licensees to conduct audits of their radiation therapy quality assurance programs (10 NYCRR 16.24). Specifically, 16.24(a)(4) states the required frequency and type of audits which are to be conducted. Licensees have two options: 1) external audits must be conducted every 12 months by radiation therapy physicists possessing the qualifications specified in 10 NYCRR 16.122 and physicians who are active in the practice and type of radiation therapy conducted by the licensee or registrant, or, 2) the licensee or registrant can conduct internal audits at intervals not to exceed 12 months and have an audit performed by the American College of Radiology or, a program found equivalent by the Department, at intervals not to exceed five years.

Accreditation - Private insurers: BCBS MA

MASSACHUSETTS
Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

BILLING GUIDELINE

Policy #: 396 **Posted: 3/11/08** **Page: 1 of 7**

Title
Radiation Therapy

There is no medical policy on this subject. Radiation therapy is covered to the extent that this type of service is generally covered by each member's benefit design. **The following billing guidelines are brought to you by Blue Cross Blue Shield of Massachusetts, for informational use.**

Definitions
Free-standing Radiation Oncology Facility: a non hospital setting that is accredited by either the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or the American College of Radiology (ACR) in accordance with the BCBSMA conditions of participation.

State laws:

California (no QMP)

Senate Bill No. 1237

CHAPTER 521

An act to add Sections 115111, 115112, and 115113 to the Health and Safety Code, relating to public health.

[Approved by Governor September 29, 2010. Filed with Secretary of State September 29, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, Padilla. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined.

Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law the department may also require registration and inspection of sources of ionizing radiation, as defined. Violation of these provisions is a crime.

This bill would, commencing July 1, 2012, require hospitals and clinics, as specified, that use computed tomography (CT) X-ray systems for human use to record, if the CT systems are capable, the dose of radiation on every CT study produced during the administration of a CT examination, as specified. The bill would require the dose to be verified annually by a medical physicist, as specified, unless the facility is accredited.

This bill would, commencing July 1, 2013, require facilities that furnish CT X-ray services to be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting

ASTRO-AAPM: Patient safety

Practical Radiation Oncology (2011) 1, 16–21

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Special Article

Improving patient safety in radiation oncology

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Received 5 November 2010; accepted 12 November 2010

Abstract Beginning in the 1990s, and emphasized in 2000 with the release of an Institute of Medicine report, health care providers and institutions have dedicated time and resources to reducing errors that impact the safety and well-being of patients. However, in January 2010, the first of a series of articles appeared in *The New York Times* that described errors in radiation oncology that grievously impacted patients. In response, the American Association of Physicists in Medicine and the American Society for Radiation Oncology sponsored a working meeting entitled "Safety in Radiation Therapy: A Call to Action." The meeting attracted 400 attendees, including medical physicists, radiation oncologists, medical dosimetrists, radiation therapists, hospital administrators, regulators, and representatives of equipment manufacturers. The meeting was co-hosted by 14 organizations in the United States and Canada. The meeting yielded 20 recommendations that provided a pathway to reducing errors and

- **Staffing levels**
- **FMEA**
- **Error reporting**
- **Accreditation**
- **Standardization**
- **Checklists**

Medical Physics Practice Guidelines

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
PROFESSIONAL POLICY:
PROCESS FOR CREATION, APPROVAL, AND REVISION OF
MEDICAL PHYSICS PRACTICE GUIDELINES

INTRODUCTION

The American Association of Physicists in Medicine (AAPM) has long advocated a consistent level of medical physics practice, and has published many guidelines and position statements toward that goal, such as Science Council Task Group reports related to calibration and quality assurance, Education Council and Professional Council Task Group reports related to education, training, and peer review, and Board-approved Position Statements related to the scope of practice, physicist qualifications, and other aspects of medical physics practice. Despite these concerted and enduring efforts, the profession does not have a clear and concise statement of the acceptable practice guidelines for routine clinical medical physics. As accreditation of clinical practices becomes more common, Medical Physics Practice Guidelines (MPPGs) will be crucial to ensuring a consistent benchmark for accreditation programs.

The AAPM will lead the development of MPPGs in collaboration with other professional societies. The MPPGs will be freely available to the general public. Accrediting organizations, regulatory agencies and legislators will be encouraged to reference these

TG reports vs MPPGs

TG reports are:

- Intended to be technical reference for medical physicists – compendia of the known science on a topic.
- Written by a core group of subject-matter experts
- Reviewed by subject-matter committee and approved by one Council

TG reports vs MPPGs

MPPGs are:

- Developed following a structured process to become consensus practice guidance documents
- Developed with cross-Council participation
- Open for review/comment by ALL members
- Intended to be adopted by regulatory agencies and accrediting entities
- Freely available to ALL – including the public

MPPG development process

1. Subcommittee on Practice Guidelines oversees the process, includes members from TPC, IPC and GRAC.
2. Unique TG formed for each MPPG, with broadly representative membership
3. Common framework for all MPPGs
4. Other organizations invited to participate
5. Drafts reviewed by all Councils and by ALL members through Open Comment period
6. Final approval by Professional Council

MPPG framework

- Staffing needs, qualifications, and responsibilities clearly described
- Required resources and equipment
- Staff training and validation methods
- Each recommendation to include relevant references *and example case scenario*

Initial MPPGs

- Imaging: CT protocol management and review
- Therapy: Linac-based imaging
- Possible: Safety checklists – principles of design, validation, and implementation

Path forward?

- Minimum standards for practicing clinical medical physics will likely have the force of regulation in most states within a decade.
- Major components:
  - Minimum education & training requirements
  - Board certification
  - Peer review at regular intervals
  - Continuing professional development (MOC)
- Error prevention programs will gain more prominence.

How do we respond?

- **If we (AAPM) do not define our profession, others will do it for us.**
- Current efforts:
  - Licensure / registration with strong template
  - ASTRO/ACR/IAC/TJC – strong accreditation
  - Develop Medical Physics Practice Guidelines
  - Work with CRCPD (SSRs) & FDA (devices)
  - Congress:
    - CARE bill for Training & Education standards
    - Tie Medicare funding to accreditation