

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
CAMPS
October 2010

Outline

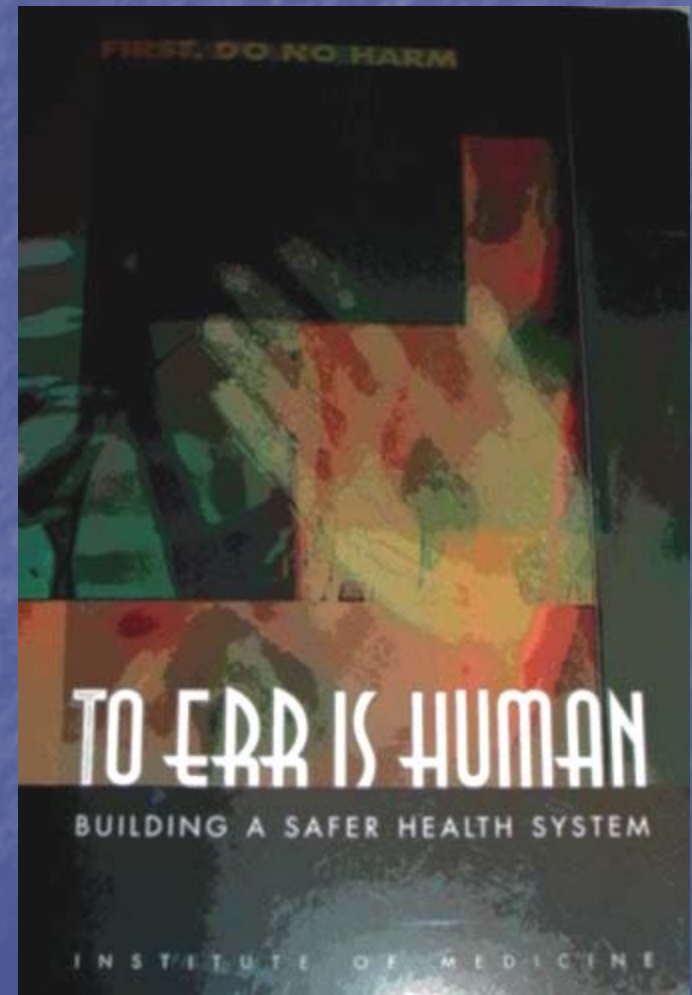
- The national (and international) focus on medical errors and quality in health care
- Federal legislative initiatives
- State regulatory changes / legislation
- Private insurance companies
- Where do we go from here?

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 $\approx 98,000$ 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
INSTITUT
DE RADIOPROTECTION
ET DE SÛRETÉ NUCLÉAIRE

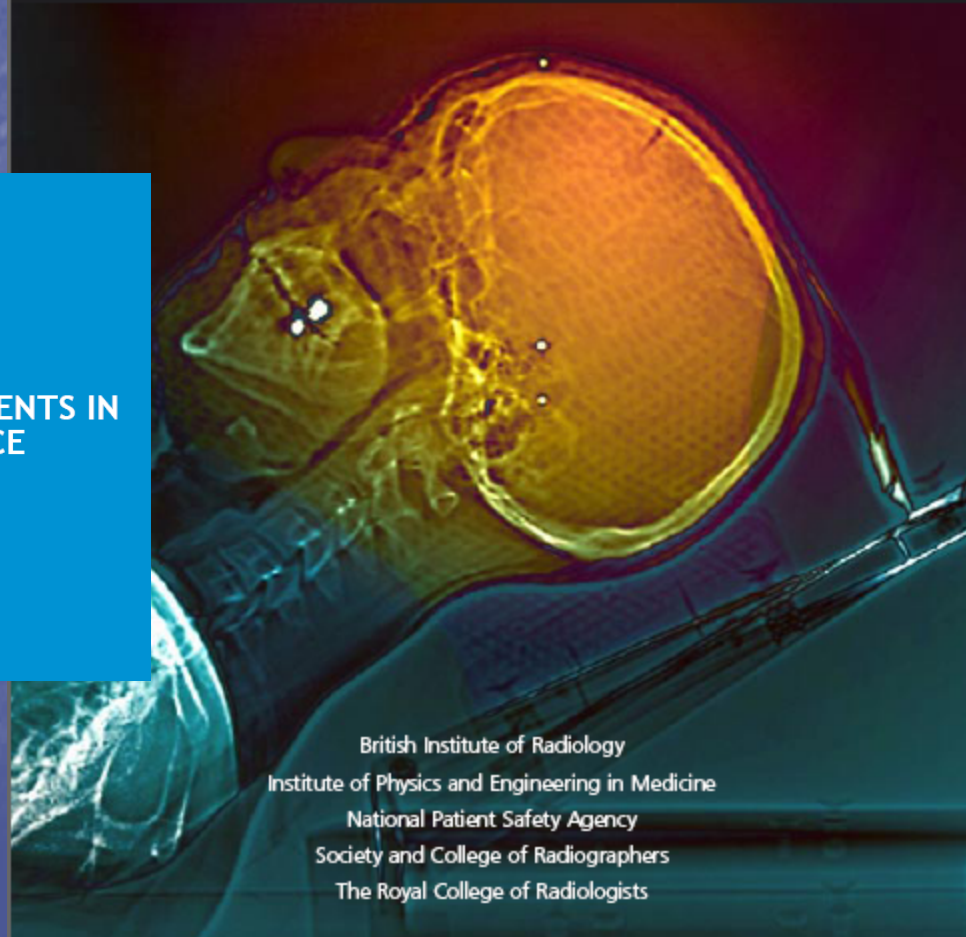
LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

25 January 2008 / Paris

Sylvie Derreumaux, IRSN



Towards Safer Radiotherapy

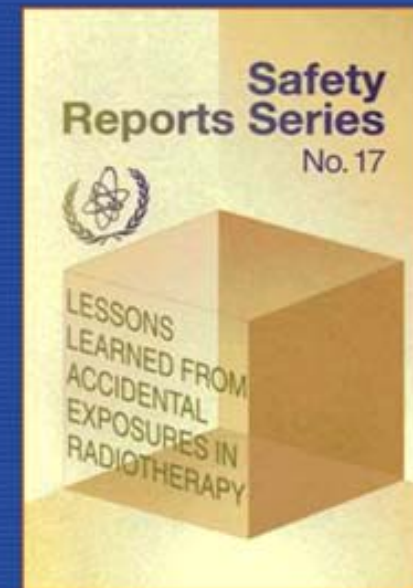


British Institute of Radiology
Institute of Physics and Engineering in Medicine
National Patient Safety Agency
Society and College of Radiographers
The Royal College of Radiologists

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”?



Errors & the AAPM



The American Association
of Physicists in Medicine

Celebrating the present
Preparing for the future
Houston, Texas • July 27 - 31, 2008



The AAPM

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Work Group on Prevention of Errors in Radiation Oncology

email: <2008.zWGPE@aapm.org> | www: [WGPE Website](#)

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AAPM Board

- ⊕ Science Council
- ⊕ Therapy Physics
 - ⊕ Quality Assurance and Outcome Improvement SC
 - ⊕ **Work Group on Prevention of Errors in Radiation Oncology** [Status]
 - TG100 Method for Evaluating QA Needs in Radiation Therapy [Status]

» Active Task Group listing

» AAPM Members Only Information

Bylaws	Not Referenced.
Rules	Not Referenced.
Approved Date(s)	Start: 1/20/2005 End: n/a

Members - 2008 Roster

CO Dunscombe, Peter B.	
10/5/2005	Chair

Increased media focus

The New York Times

Health

WORLD

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OPINION

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with [ulcers](#) in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final

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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 CoxHealth 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 are 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 committee, good morning and thank you for the opportunity to testify today on Medical Radiation Safety Issues.

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



Congressional focus

RADIOACTIVE ROULETTE:

How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety



**A report by the Staff of Edward J. Markey (D-MA)
Chairman, Subcommittee on Energy and Environment
Energy and Commerce Committee
U.S. House of Representatives
March 18, 2010**



**EMBARGOED UNTIL THURSDAY MARCH 18, 2010
12:01 AM**

Last summer

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

Last fall



U.S. SENATE COMMITTEE ON VETERANS' AFFAIRS

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Hearing

Philadelphia VA Medical Center's Terminated Cancer Treatment Program

UNITED STATES SENATE
COMMITTEE OF VETERANS' AFFAIRS

Field Hearing on Philadelphia VA Terminated Cancer Treatment Program

June 29, 2009, 10:00 AM

Philadelphia VA Medical Center

[Click Here to Listen to Part 1 of the Hearing](#)

[Click Here to Listen to Part 2 of the Hearing](#)

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Increased device regulation likely:

The New York Times

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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.

Increased device regulation likely:

FDA Public Meeting

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

June 9-10, 2010

8:00 am – 5:00 pm

Hilton Gaithersburg
620 Perry Pkwy
Gaithersburg, MD 20877



HOME PAGE TODAY'S PAPER VIDEO MOST POPULAR TIMES TOPICS

The New York Times **Health**

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION

RESEARCH FITNESS & NUTRITION MONEY & POLICY VIEWS

Safety Features Planned for Radiation Machines

By WALT BOGDANICH
Published: June 9, 2010

GAITHERSBURG, Md. — Manufacturers of [radiation therapy](#) equipment said at a patient-safety conference here Wednesday that within the next two years their new equipment and the software that runs it would include fail-safe features to help reduce harmful radiation overdoses and other mistakes.

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Regulation of devices is not enough:

International Commission on Radiological Protection

Information abstracted from
ICRP Publication 86

Available at www.icrp.org

Task Group: P. Ortiz, P. Andreo, J-M. Cosset, A. Dutreix,
T. Landberg, L.V. Pinillos, W. Yin, P.J. Biggs

ICRP INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

- Most are process failures resulting from inadequate SOPs, staffing, resources:

- Comprehensive QA is crucial in prevention and involve clinical, physical and safety components:
- Its implementation requires
 - complex multi-professional team work
 - clear allocation of functions and responsibilities
 - functions and responsibilities understood
 - number of qualified staff, commensurate to workload

ICRP INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

Learning from errors:

- Most are process failures:

ICRP Publication 86

Table 3. Classes and frequencies of accidental exposure in radiotherapy

<i>Accidental exposures in external beam therapy</i>	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 ACMP-AAPM definition of QMP

CARE bill

111TH CONGRESS
2D SESSION

S. 3737

To amend the Public Health Service Act and title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

111TH CONGRESS
1ST SESSION

H. R. 3652

To amend the Public Health Service Act and title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

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 Alliance for CARE

- American Association of Medical Assistants
- American Association of Medical Dosimetrists
- American Association of Physicists in Medicine
- American College of Medical Physics
- American Registry of Radiologic Technologists
- American Society of Radiologic Technologists
- Association of Educators in Imaging and Radiologic Sciences
- Association of Vascular and Interventional Radiographers
- Cardiovascular Credentialing International
- Joint Review Committee on Education in Cardiovascular Technology
- Joint Review Committee on Education in Diagnostic Medical Sonography
- Joint Review Committee on Education in Radiologic Technology
- Joint Review Committee on Education Programs in Nuclear Medicine Technology
- Nuclear Medicine Technology Certification Board
- Section for Magnetic Resonance Technologists of International Society of Magnetic Resonance in Medicine
- Society of Nuclear Medicine-Technologist Section
- Society for Radiation Oncology Administrators
- Society for Vascular Ultrasound
- Society of Diagnostic Medical Sonography
- Society of Invasive Cardiovascular Professionals

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:

AMERICAN SOCIETY FOR RADIATION ONCOLOGY
2010 YEAR IN REVIEW

TARGET SAFELY

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 screenshot shows the ACR website header with the logo "ACR AMERICAN COLLEGE OF RADIOLOGY" and the tagline "QUALITY IS OUR IMAGE". Navigation links include "LOGIN", "RESIDENTS", "ABOUT US", "CAREER CENTER", "PATIENT INFO", "MEDIA ROOM", "MY PROFILE", and "JOBS AT ACR". A search bar is visible with "SEARCH SITE" and "SEARCH" buttons. The main content area features a "Print Page?" button and a breadcrumb trail: "Home | News & Publications | Current ACR News | ACR Mandatory Accreditation House EC". The article title is "ACR Calls for Mandatory Accreditation of All Advanced Imaging and Radiation Oncology Providers".

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/ACMP

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

Committee Tree

Joint Medical Physics Licensure Subcommittee

[AAPM Members - Login for access to additional information](#)

AAPM Board

⊕ Professional Council

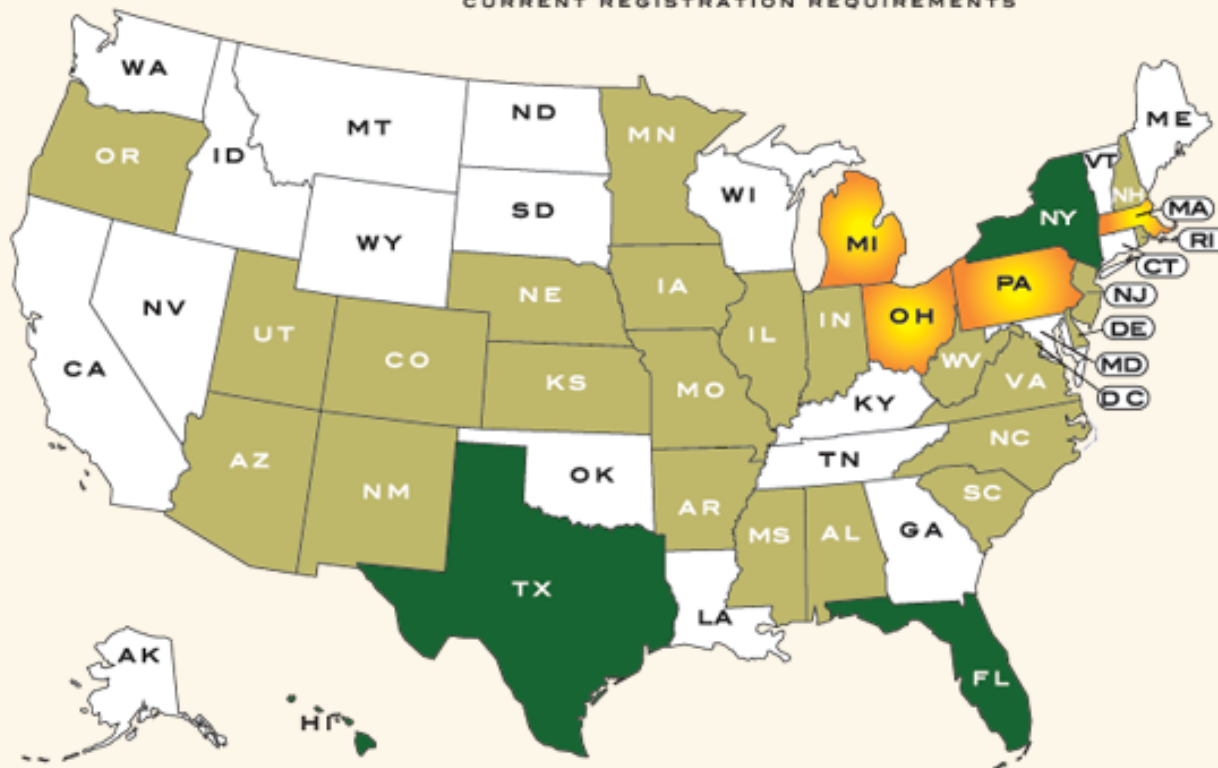
⊕ Clinical Practice

⊖ **Joint Medical Physics Licensure Subcommittee** [Status]

State regulations

Government Affairs

State Regulations and Licensure



Licensure

- NY, FL, TX, HI.
- NY law:



Medical Physics

[Online Registration Renewal](#)
[Laws, Rules & Regulations](#)
[License Requirements](#)

Education Law

Article 166, Medical Physics Practice

[§ 8700. Introduction.](#) | [§ 8701. Definitions.](#) | [§ 8702. Definition of "practice of medical physics".](#) | [§ 8703. Use of the title "professional medical physicist".](#) | [§ 8704. State committee for medical physics.](#) | [§ 8705. Requirements and procedures for professional licensure.](#) | [§ 8706. Limited permits.](#) | [§ 8707. Exemptions.](#) | [§ 8708. Licensure without examination.](#) | [§ 8709. Separability.](#)

§ 8700. Introduction.

This article applies to the profession of medical physics. The general provisions for all professions contained in article one hundred thirty of this title apply to this article.

NY Licensure

- 18-month phase-in period, then Board certification required.

§ 8705. Requirements and procedures for professional licensure.

To qualify for a license as a professional medical physicist, an applicant shall fulfill the following requirements:

1. Application: file an application with the department;
2. Education: have received an education including a master's or doctoral degree from an accredited college or university in accordance with the commissioner's regulations. Such person shall have completed such courses of instruction as are deemed necessary by the medical physics specialty in which the applicant has applied for a license;
3. Experience: have experience in his or her medical physics specialty satisfactory to the board and in accordance with the commissioner's regulations;
4. Examination: pass an examination in his or her medical specialty satisfactory to the board and in accordance with the commissioner's regulations. The examination requirement may be waived by the board on recommendation of the commissioner for certain applicants with equivalent experience as a medical physicist;
5. Age: be at least twenty-one years of age;

Registration

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

Registration vs Licensure

- Licensure makes it illegal to practice without having demonstrated the required qualifications.
- Licensure ensures due process for any physicist accused of wrongdoing, by a group of professional peers (licensing board). With a registry, the state regulatory agency makes a unilateral decision.
- With a registry, the state agency can change the rules at any time. With licensure, changes would have to be approved by a group of our peers.
- Licensure enables the profession (through the licensing board) to remove unsafe or unethical practitioners from clinical practice.
- Neither approach impinges on the freedom to practice in non-clinical environments (research, teaching).

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.

CT: Proposed Registry

(4) Training for An Authorized Medical Physicist. The registrant for any therapeutic radiation machine subject to subsection (f) or (g) of this section shall obtain or utilize the services of an Authorized Medical Physicist and shall require the Authorized Medical Physicist to:

- (A) Be registered with the Commissioner as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and
- (B) Be certified by the American Board of Radiology in:
 - (i) Therapeutic radiological physics, or
 - (ii) Roentgen-ray and gamma-ray physics, or
 - (iii) X-ray and radium physics, or
 - (iv) Radiological physics; or
- (C) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
- (D) Be certified by the Canadian College of Medical Physics; and
- (E) Pursue continuing professional development in accordance with the guidelines from the applicable certification board.

(5) Training for an Authorized Medical Dosimetrist. The registrant for any therapeutic radiation machine subject to subsection (f) or (g) of this section shall obtain or utilize the services of an Authorized Medical Dosimetrist and shall require the Authorized Medical

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.

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

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.

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.

Medical Physics Practice Standards

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.



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 Standards
 - Work with CRCPD (SSRs) & FDA (devices)
 - Congress:
 - CARE bill for Training & Education standards
 - Tie Medicare funding to accreditation