Medical Physics Practice Guidelines in Clinical Medical Physics: Defining an appropriate “floor”

Per Halvorsen, MS, FACP, FAAPM
March 2015

Outline

- How we got here:
  - The national (and international) focus on medical errors and quality in health care
  - Federal legislative initiatives
  - State regulatory requirements
  - Private insurance companies
- Professional society initiatives including AAPM
  - Medical Physics Practice Guidelines
- The importance of supervision standards
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 late 1999, 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 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”?
Increased media focus

The New York Times
Health

THE RADIATION BOOM
Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 25, 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

March 16, 2006
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.
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

U.S. Senate Committee on Veterans’ Affairs

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 25, 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
A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

By WALT BOGDANICH and KRISTINA RIBELO

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.

Marcia 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.

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 panel, this morning and thank you for the opportunity to testify today on Medical Radiotherapy 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 – of the unhelpful kind....

RADIOACTIVE ROULETTE:
How the Nuclear Regulatory Commission’s Cancer Patient Radiation Rules Gamble with Public Health and Safety


EMBARGOED UNTIL THURSDAY MARCH 18, 2010 12:01 AM

Increased device regulation likely:

The New York Times

February 10, 2010
F.D.A. to Increase Oversight of Medical Radiation
by JUXT BOUDREAU 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.
Regulation of devices is not enough:

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

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

ICRP Publication 86

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
  - CMS is charged with approving accreditation programs
  - Does not include x-ray, fluoroscopy, sonography, or anything in radiation oncology
  - Does not apply to hospitals
Accrediting bodies approved by CMS under MIPPA:

- American College of Radiology
- Intersocietal Accreditation Commission
- The Joint Commission
- RadSite (new)

*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 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.
AAPM’s position:

Professional/Education/Science Policies

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<tr>
<th>POLICY NUMBER</th>
<th>POLICY NAME</th>
<th>POLICY DATE</th>
<th>SUNSET DATE</th>
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<tbody>
<tr>
<td>PP 27-A</td>
<td>Accreditation of imaging and radiation therapy facilities</td>
<td>4/19/2013</td>
<td>3/31/2018</td>
</tr>
</tbody>
</table>

Policy source:
The American Association of Physicists in Medicine (AAPM) believes that accreditation of imaging and radiation therapy services by nationally recognized accrediting programs serves the best interests of patients. AAPM supports conditioning healthcare payments on accreditation status after an appropriate time interval for facilities and accrediting programs to complete the accreditation process. Accreditation must specify qualifications and roles for personnel, including a Qualified Medical Physicist as defined by Professional Policy PP 1.

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

BILLING GUIDELINE

Policy #: 306  
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 (CT)

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 organization.
ASTRO-AAPM: Patient safety

Special Article

Improving patient safety in radiation oncology

William R. Hendee PhD, Michael G. Herman PhD

*Medical College of Wisconsin, Rochester, Minnesota
1Department of Radiation Oncology, Mayo Clinic, Rochester, Minnesota

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.

ASTRO White Papers

Special Article

Safety considerations for IMRT: Executive summary

Jean M. Moran PhD, Melanie Dempsey MS, Avraham Elsbuchi MD, Benedick A. Fraass PhD, James M. Galvin DSc, Geoffrey S. Ibbott PhD, Lawrence B. Marks MD

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Received 19 April 2011; accepted 27 April 2011
Medical Physics Practice Guidelines

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
- Updated regularly – sunset dates / revision #
- Freely available to ALL – not just AAPM

MPPG vision/scope

2. Vision

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 MPPGs when defining their respective requirements.

3. Scope

MPPGs are intended to provide the medical community with a clear description of the minimum level of medical physics support that the AAPM would consider prudent in all clinical practice settings. Support includes but is not limited to staffing, equipment, machine access, and training. These MPPGs are not designed to replace extensive Task Group reports or review articles, but rather to describe the recommended minimum level of medical physics support for specific clinical services.
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
Initial MPPGs

In print (JACMP):
- Imaging: CT protocol management and review
- Therapy: Linac-based imaging

In journal review:
- Safety Checklists
- Physicist Supervision (residents etc)
- TPS dose model QA
4. Implementation Guidelines

I. Staffing

Approximate time requirements needed for implementation, maintenance and quality assurance of each IORT program type (per each IORT system) are provided below. Estimates are provided as general reference values only, and are not intended to justify site-specific staffing models or physics time for specific billing codes. “Acceptance/Commissioning” includes all activities needed for IORT program implementation, including documentation. “Documentation” refers to creation of a formal commissioning report, and drafting of policies and procedures specific to clinical use and routine quality assurance of IORT (including creating QA forms and templates). “Ongoing support” includes all activities needed for maintenance of an established IORT program (e.g., routine quality assurance, troubleshooting, upgrades, service/repairs).

1. Two-dimensional MV imaging systems

- Acceptance/Commissioning/Documentation: 18–36 hours
- Ongoing support: 25–50 hours annually

2. Two-dimensional kV imaging systems

- Acceptance/Commissioning/Documentation: 18–36 hours
- Ongoing support: 25–50 hours annually

3. Three-dimensional MV imaging systems

- Acceptance/Commissioning/Documentation: 18–36 hours
- Ongoing support: 100–125 hours annually

II. Equipment

Quality assurance phantoms and tools must provide reliable values of the measured parameters and can be used to judge whether tolerance criteria have been achieved. In many cases, manufacturers of IORT systems provide quality assurance phantoms which can be used for quality assurance purposes. In-house and commercial phantoms specifically designed for IORT are also available and, when coupled with automated
Initial MPPG excerpt

Medical Physicist Assistants: An inevitable consequence of the broader trend toward extenders in healthcare?
ACR Technical Standards:

**III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

The medical physicist may be assisted by other properly trained individuals in obtaining test data for performance monitoring. These individuals must be properly trained and approved by the medical physicist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The tests will be performed by or under the general supervision of the medical physicist, who is responsible for and must review, interpret, and approve all data and provide a signed report.

**NJ regs:**

**SUBCHAPTER 22 QUALITY ASSURANCE PROGRAMS FOR MEDICAL DIAGNOSTIC X-RAY INSTALLATIONS**

7:28-22.1 Purpose, scope and applicability

(a) The purpose of this Subchapter is to increase protection to the public and radiation workers from unnecessary exposure to radiation and to reduce the occurrence of misdiagnosis caused by faulty equipment and operator error.

(b) This Subchapter establishes requirements for the development and implementation of quality assurance programs to ensure that registrants of diagnostic x-ray equipment who perform diagnostic x-ray procedures in the healing arts achieve consistent high quality imaging and improve diagnosis while reducing unnecessary radiation to the patients and workers. This Subchapter further establishes certain responsibilities of registrants of radiation sources used in the practice of diagnostic radiology. This Subchapter also establishes the qualifications and training requirements for medical physicists, medical physicist assistants and qualified individuals designing or implementing quality assurance programs in accordance with this subchapter. Certification requirements and associated fees are also established for medical physicists and medical physicist assistants.
MPAs

NJ regs:

Only a person who holds a valid Certificate issued by the Department in accordance with N.J.A.C. 7:26-22.13(a), meets one of the criteria contained in (c) 1 through 5 below and who meets criterion 6 below may perform the duties of a "qualified medical physicist assistant in radiography":

1. Is currently ARRT certified in general radiography or holds a current New Jersey license as a diagnostic radiologic technologist and has five years of experience as a practicing diagnostic radiologist, one year of which shall include performing quality control tests on radiographic equipment;

2. Is currently ARRT certified in both general radiography and in quality management with three years of experience as a practicing diagnostic radiologic technologist;

3. Has a bachelors degree from an accredited college or university in biology, chemistry, radiation sciences, physics, engineering or mathematics and four years of technical experience performing quality control tests on radiographic equipment in the field of radiological health;

4. Has a master's degree or a doctorate degree from an accredited college or university in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and two years of technical experience performing quality control tests on radiographic equipment in the field of radiological health;

Supervision / MPAs

Draft language for TX licensure hearings:

The Medical Physicist Assistant (MPA) is an individual who has completed relevant didactic education (Bachelor's or higher college degree from an accredited college or university and/or certification as a Radiologic Technologist or Radiation Therapist), and has attained practical clinical medical physics knowledge through documented specific training and technical experience in a program supervised by a QMP. The MPA performs tasks to support the efficiency of a QMP in the professional practice of medical physics. In all such circumstances, the MPA must be appropriately supervised and the range of tasks must be carefully defined by a QMP who is certified in the same subfield of practice. Levels of supervision provided (personal, direct, or general) will vary depending on the specific task, experience of the MPA and professional judgment of the QMP supervisor. All medical physics tasks performed by the MPA must be reviewed in a timely manner, and reports must be co-signed by the QMP supervisor, who assumes full responsibility and liability for the submitted content.

Under consideration by the AAPM is: (1) the number of MPAs that may be supervised by an individual QMP, and (2) the categories of advanced tasks/procedures that require direct or personal supervision. The overall intent of this position statement and future Medical Physics Practice Guideline is to enhance the safety of patient care through the provision of high-quality medical physics services in a cost-effective manner.
Supervision / MPAs

Board of Directors approved motion:

- Action Item: BE IT MOVED: That the AAPM work to develop an appropriate policy and guidance related to the role, training and supervision of Medical Physicists Assistants (MPAs) in supporting clinical medical physics work under the supervision of a Qualified Medical Physicist. Such guidance shall include, but may not be limited to:
  1. Developing a Medical Physics Practice Guideline on supervision for MPAs and other support staff (lead: Professional Council).
  2. Developing an AAPM Position Statement on the appropriate role, training and supervision of MPAs (lead: Professional Council).
  3. Interacting with regulatory and licensing bodies and with other professional societies to advocate for the AAPM’s position related to the appropriate role, training and supervision of MPAs (lead: Administrative Council).
  4. Developing the educational curriculum for MPAs (lead: Education Council).

Motion was seconded and approved; 31 yes, 0 no, 1 abstain.

Supervision / MPAs

Approved AAPM Policy 29-A:

THE AAPM
Professional/Education/Science Policies

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<th>POLICY NAME</th>
<th>POLICY DATE</th>
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Policy Issued:
- AAPM Board of Directors’ Online Vote

Policy Text:
- A Qualified Medical Physicist (QMP) is an individual who is competent to independently provide clinical professional services in one or more of the subjects of medical physics, including Diagnostic Medical Physics, Nuclear Medical Physics, Therapeutic Medical Physics, or Medical Health Physics. MPAs have not academic and training requirements, and have been granted certification in a specific subject of medical physics by an appropriate certification body as described in AAPM Professional Policy 1.

Some institutions may use the services of individuals who are not a qualified medical physicist for certain clinical activities. The services they provide, and the location where they provide these services are limited based on facility and patient care considerations, and the availability of direct or personal QMP supervision where necessary.

The Medical Physicist Assistant (MPA) is an individual who has completed relevant academic education (Bachelor’s or higher college degree from an accredited college or university) and certification as a Radiation Therapy Technologist, and has attained practical clinical medical physics knowledge through specific training and technical experience in a program supervised by a QMP. The MPA performs tasks in support of a QMP in the professional practice of clinical medical physics. For all such responsibilities, the MPA must be appropriately supervised and the range of tasks must be carefully defined by a QMP via a certificate in the same subject of practice in which the MPA is working. Levels of supervision provided personal, direct, or general, will vary depending on the specific task, experience of the QMP and professional judgment of the QMP supervisor. In accordance with guidance of the forthcoming Medical Physics Practice Guideline on this subject, all medical physics tasks performed by the MPA must be reduced in intensity, and reports must be co-signed by the QMP, supervisor with assumed full responsibility and liability for the submitted content.

- AAPM Professional Policy 1
Supervision

- Strong precedent in medicine – CMS has defined 3 levels of supervision: general, direct, personal.
- AAPM’s Professional Policy 18 incorporates the CMS supervision levels for medical physics – will be replaced by two MPPGs:
  - MPPG #4 defines supervision for residents and other “QMP-track physicists”
  - MPPG #7 will define supervision for support personnel such as Medical Physicist Assistants.

Supervision

QMP-track
- Gradual transition toward independent practice

Others – Medical Physicist Assistants
- Risk-informed delegation of tasks
- Data collection / inventory / etc
- Analysis and professional judgment: QMP
Supervision

Responsibility
- QMP retains full responsibility for the work
- QMP designs supervision plan & assesses competence to perform tasks
- Limits on ratio of supervised individuals per QMP

Path forward?
- Minimum standards for practicing clinical medical physics will likely have the force of regulation in most states within a decade.
- May be accomplished through mandatory accreditation
- Accreditation programs need practice guidelines / standards
- AAPM should be the source of such guidelines in collaboration with others