



## MASSACHUSETTS RADIOLOGICAL SOCIETY, INC.

CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY

P. O. Box 9132, Waltham, MA 02454-9132 • (781) 434-7313 • Fax: (781) 893-2105 • www.massrad.org

### **PRESIDENT**

Christoph Wald, MD, PhD  
Lahey Clinic  
Department of Radiology  
41 Mall Road  
Burlington, MA 01805  
Office: 781-744-8170  
Fax: 781-823-0096  
Christoph.wald@lahey.org

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Sanjay Shetty, MD, MBA

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Philip Rogoff, MD, FACR

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Alexander Norbash, MD, FACR  
Boston University  
FGH Building, 3<sup>rd</sup> Floor  
820 Harrison Avenue  
Boston, MA 02118  
617-638-6610  
617-638-6616  
norbash@bu.edu

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Arthur Waltman, MD, FACR

### **Legal Counsel:**

Edward J. Brennan, Jr., Esq.  
80 Washington St., Suite O-53  
Norwell, MA 02061  
(781) 982-9143  
Fax: (617) 982-7037  
ebrennan@ejblawoffice.com

### **Chapter Administrator:**

Ginny DuLong  
860 Winter Street  
Waltham, MA 02451  
(781) 434-7313  
Fax: 781-893-2105  
vdulong@mms.org

September 9, 2011

LouAnn Stanton  
Office of the General Counsel  
Department of Public Health  
250 Washington Street  
Boston, MA 02108

Re: Proposed Amendments to the Massachusetts Regulations for the  
Control of Radiation (105 CMR 120.000 et. seq)

Dear Ms. Stanton:

These comments regarding proposed amendments to the Massachusetts Regulations for the Control of Radiation are submitted on behalf of the Massachusetts Radiological Society ("MRS"), the state component society of the American College of Radiology ("ACR"), which represents over 800 diagnostic radiologists, radiation therapists and medical physicists practicing in Massachusetts.

The Massachusetts Radiological Society supports the need to update the Commonwealth's Radiation Safety Regulations. We appreciate the massive amount of work that has gone into developing these proposals and we welcome the opportunity to submit these comments.

### **I. Fluoroscopic X-Ray Systems, 105 CMR 120.405(K) Operator Qualifications.**

It is imperative, in the interests of image quality and patient safety, that the operator of fluoroscopic x-ray systems be formally trained and qualified in the areas of technology and radiation safety.

The proposed regulations would add physician assistants to the list of non-physicians who may perform fluoroscopic procedures. This provision is a product of discussions initiated by the Board of Registration in Physician Assistants, the Board of Registration in Medicine and the Division of Radiation Control working with various stakeholders to develop education and supervision requirements for qualified physician assistants to perform fluoroscopy procedures under the supervision of a physician. The MRS would make the following recommendations regarding operator qualifications.

1. In Section 120.405(K) (3) there is delineated the educational preparation, clinical training and competency assessment for physician assistants to qualify to perform fluoroscopy. The regulations require 40 hours of clinical training, but do not specify a number of hours for didactic education. The MRS believes that a minimum number of hours of education should be required for a meaningful education program. The ACR Technical Standards for Management of the Use of Radiation in Fluoroscopic Procedures states that all ancillary personnel using fluoroscopy should complete 40 hours of didactic education in the subject matters listed in the proposed regulations (a copy of that portion of the ACRs statement regarding ancillary personnel is attached). Not only is our recommendation consistent with ACR standards, it is also consistent with the joint statement of the American Academy of Physician Assistants and the American Society of Radiologic Technologists entitled “Fluoroscopy Educational Framework for the Physician Assistant”. We would urge that Section 120.405(K)(3)(a) be amended to read: “Didactic Content, a minimum of 40 hours of education consisting of the following topics:”
2. We note that the proposed regulations do not address physician supervision of qualified ancillary personnel who may perform fluoroscopy. This may be viewed as the domain of the appropriate regulatory boards. However, due to safety issues inherent with radiation, the MRS would urge that these proposed regulations be amended to insert a provision that would require that all procedures involving fluoroscopy performed by qualified ancillary personnel, such as physician assistants, be under the supervision of a radiologist or qualified physician. Such supervision must be direct or personal. This recommendation reflects the ACR Technical Standards regarding the use of radiation in fluoroscopic procedures and is included in the above referenced Standard relating to ancillary personnel, which is attached to these comments.

## II. Further Comments

1. 105 CMR 120.402 Definitions. Under the definition “Qualified Medical Physicist”, please strike out clause (5). There is an inconsistency with Section 120.433(D) governing radiation therapy. The Radiation therapy regulations do not contain clause (5) and we believe the definition of “Qualified Medical Physicist” should be consistent and there is no need for clause (5) in Section 120.402.
2. 105 CMR 120.403(A) (2) (c). We would recommend that this clause regarding surveys, preventative maintenance or calibration should be clarified to make clear that a service provider cannot perform surveys.

The MRS would recommend that sub-clause 2 of clause(c) be changed to read as follows:

“The surveys or calibration shall be performed by a qualified medical physicist.”

A new sub-clause 3 should be inserted to read:

“3. The preventative maintenance or calibration shall be performed by a registered service provider as specified in 105 CMR 120.026 or under the supervision of or by a qualified medical physicist.”

3. 120.407(G) (4). Similar to our recommendation regarding the above referenced 120.403(A) (2) (c), we would recommend that this clause (G) (4) be clarified to make clear that a service provider cannot perform surveys.
4. 105 CMR 120.409 Computer Tomography X-ray Systems. The MRS would recommend that the first sentence of Section 409 be changed to read:

“Any facility offering diagnostic CT services after April 30, 2011 shall have ACR accreditation.”

This recommendation would clarify that non-diagnostic CT scanners in health care, including dedicated radiotherapy simulators, core beam CT systems on linear accelerators or any other system which is not used for medical diagnosis is not required to obtain ACR accreditation.

5. 105 CMR 120.409(D) (1) Clarification of a CT Operator. We would recommend that this clause be clarified to be consistent with other provisions of the regulations to recognize that a licensed physician can operate a CT. We would recommend that the clause be changed by inserting after the word “operated” the words “by a licensed physician or”.
6. 105 CMR 120.410 (C). Bone Densitometry. The MRS would recommend that radiological technologists operating bone densitometry systems should have appropriate training. We would recommend that those who are not ARRT or ISCD certified in bone densitometry have demonstrated training, such as 8 hours of initial training and 4 hours CME every 2 years.
7. 105 CMR 120.432 – Definitions. The MRS would recommend that a definition for MODE be added to the regulations. This would eliminate confusion as to whether changing from 6MV Photon to 10MV Photon constitutes a MODE change. The definition we propose is the common understanding of the term.

“MODE In External Beam Radiation Therapy means the beam type employed (e.g. Photon vs. Electron beam).”

8. 105 CMR 120.435(E) (3). The MRS would recommend that “calendar day” be replaced with the term “business day”. We believe that this is the intent of the regulation and it would preclude a violation of a misadventure that occurs on a Friday afternoon at 4:30 that is reported on the following Monday morning.
9. 105 CMR 120.502 – Definitions. In the definition of “Authorized Medical Physicist” we would recommend that clause (1) be amended by striking out reference to 120.529. Section 120.525A includes a requirement for certification or “passing an examination” which makes the timing of training irrelevant, and the reference to 120.529 may technically preclude physicists with current certification (and thus fully credentialed QMPs) from work if their training was more than seven years ago.

The MRS appreciates the opportunity to present these comments. If you need further information or explanation regarding our comments, please contact us.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Christoph Wald'.

Christoph Wald, M.D., PhD,  
President  
Massachusetts Radiological Society

A handwritten signature in black ink, appearing to read 'Martin Fraser'.

Martin Fraser, MS, FACR  
Physicist Member of the Executive  
Committee  
Massachusetts Radiological Society

American College of Radiology

Standard for Management of the Use of Radiation in Fluoroscopic

Procedures under Section III, E - Other Ancillary Personnel.

"Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform fluoroscopic examinations or fluoroscopically guided imaging procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state and federal regulations.

All ancillary personnel using fluoroscopy should be credentialed for those fluoroscopic examinations or procedures and should have completed 40 hours of didactic education or its equivalent in digital image acquisition and display, contrast media, fluoroscopic unit operation and safety, image analysis, radiation biology, radiation production and characteristics, and radiation protection; and 40 hours of clinical experience supervised by a radiologist or medical physicist. Required CME for other ancillary personnel performing fluoroscopy should include education in radiation dosimetry, radiation protection, and equipment performance related to the use of fluoroscopy."

The web link to the full document is:

[http://www.acr.org/SecondaryMainMenuCategories/quality\\_safety/guidelines/med\\_phys/management\\_fluoro\\_procedures.aspx](http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/management_fluoro_procedures.aspx)  
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