

Massachusetts Regulations for the Control of Radiation: Proposed Amendments to 105 CMR 120.000

**Public Health Council
February 8, 2012**



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Outline

- I. Review of Need for these Amendments
- II. Public Hearing September 6, 2011
- III. Overview of Comments Received and Response to Comments
- IV. Request for PHC Approval for Final Amendments

I. The need for regulatory amendments

- Implement many new requirements imposed by the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA)
- Provide new curriculum and training requirements to authorize physician assistants to perform fluoroscopic procedures under their scope of practice agreement with their supervising physician
- Clarify existing regulations

II. Public Comments

- Following approval from the PHC to proceed to public comment on draft regulations, a hearing was held on September 6, 2011 at 250 Washington Street, Boston
- The official comment period was through September 9, 2011, however late comments were also accepted
- Fifty-one sets of written comments were received
- Thirty-two people attended the hearing, five of which provided oral testimony
- After careful review and analysis of comments, the Department determined that the proposed regulations do not require significant changes, however some modifications were made based on comments received

III. Overview of Comments Received and Response to Comments

Comment	Response
<p>Two parties made comments suggesting that we change the definition of qualified medical physicist to include the areas of certification in medical physics offered by the American Board of Radiology.</p>	<p>These comments have been accepted and incorporated into the revised regulations.</p>
<p>One party requested that the review of written safety procedures be changed from annual to biannual to be consistent with JACHO.</p>	<p>This change has not been made because while some facilities such as hospitals have reviews by the Joint Commission biannually 105 CMR 120.00 applies to all medical facilities. The Department believes that annual review is important.</p>

III. Overview of Comments Received and Response to Comments

Comment	Response
Two parties requested clarification of physics surveys.	The revised regulations have been clarified in response to these comments.
DPH received numerous comments requesting modifications to language in the Administrative Controls section, for example “entrance skin exposure rates” and “radiation protection equipment.”	The language proposed by DPH is consistent with the Suggested State Regulations offered by the Conference of Radiation Control Program Directors (CRCPD). The CRCPD strives for consistency in regulatory provisions across all states.

III. Overview of Comments Received and Response to Comments

Comment	Response
<p>31 parties requested that nurse practitioners (1) be allowed to assist with fluoroscopic procedures consistent with a Board of Registration in Nursing advisory opinion and 105 CMR 130.900. and (2) for authority to perform all fluoroscopic procedures consistent with the new authority granted to PAs.</p>	<p>(1) A clarification was added to the fluoroscopic x-ray section on operator qualifications which states that nothing shall prohibit a nurse practitioner from practicing as a first assistant in cardiac catheterization procedures within their lawful scope of practice</p> <p>(2) The Department is committed to working with the Board of Registration of Nursing to determine the appropriate curriculum for NPs to enable expanded fluoroscopic authority similar to that now granted to PAs.</p>
<p>Two parties commented that staff who operate cone beam dental systems include certified oral surgical assistants.</p>	<p>This change has not been made following discussions with the Board of Registration in Dentistry which is in the process of amending regulations on who may operate cone beam dental systems.</p>

III. Overview of Comments Received and Response to Comments

Comment	Response
<p>Two parties requested clarification of QA/QC tests for CT systems.</p>	<p>The language proposed by DPH is consistent with the Suggested State Regulations offered by the Conference of Radiation Control Program Directors (CRCPD). The CRCPD strives for consistency in regulatory provisions across all states.</p>
<p>Two parties requested removal of a requirement in the bone densitometry section because they were concerned that it would limit operators to licensed radiologic technologists and not those certified by the International Society for Clinical Bone Densitometry (ISCD).</p>	<p>These changes were not necessary because the section does state that bone densitometry technologists certified by ISCD may operate CT units designed for bone densitometry.</p>

IV. Request for PHC Approval of Amendments to 105 CMR 120.000

The Department respectfully requests final adoption of 105 CMR 120.000, as amended. If approved, the Department will file 105 CMR 120.000, as amended, with the Secretary of State for publication on March 2, 2012.

Questions