DPR 35
(76FR29171)

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Rulemaking Comments

From: Bhalla, Neelam
Sent: Tuesday, September 06, 2011 3:33 PM
To: Rulemaking Comments
Subject: FW: FSME-11-044 - Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations
Attachments: FSME-11-044.pdf

DOCKETED
USNRC

September 6, 2011 (3:45 pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

From: Vinson, Gibb [mailto:Gibb.Vinson@illinois.gov]
Sent: Friday, September 02, 2011 5:33 PM
To: Bhalla, Neelam
Cc: Eastvold, Paul; Perrero, Daren; Burkhart, Mary; Lynch, James
Subject: FW: FSME-11-044 - Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations

Dear NRC,

The Illinois Emergency Management Agency, Division of Nuclear Safety (the Agency), hereby submits its comments on FSME-11-044 regarding proposed changes to the medical regulations as follows:

- **In 35.13(h) and 35.14(b)(6), most states do not specify brachytherapy sources by model even though they may list a maximum possession limit for 35.400. Please clarify why this is included. In addition, we would not allow a licensee to use a product for 30 days without licensure. We would require prior approval of this to ensure that it is an approved product/source.**

- **In 35.350(c)(3), a new RSO candidate has been added. Purportedly, this individual would be an AU, AMP or ANP listed on another license or working under the supervision of a current RSO. This section needs to be changed to ensure that, if this individual is not already on a license or board certified, that he meets the laboratory, classroom and clinical experience pathway and have an attestation by a preceptor RSO.**

- **Based on input at the Houston Rulemaking Workshop, we would like to see clarification of the US NRC's intent of 35.27 with respect to implantation of permanent radioactive sources used in prostate brachytherapy. Under the rule it appears that a urologist may perform such implantation under the supervision of an AU (and not necessarily under 'direct' or 'personal' supervision). However, comments from the medical community and informal remarks from regulatory personnel suggest that such authorization is not appropriate nor intended from that rule.**

- **The Agency is not in favor of requiring preceptor attestations for candidates that are board certified. We are in favor of attestations for candidates that undergo the classroom/laboratory/experience pathway (alternate pathway).**

- **Lastly for medical events, the Agency supports a dual system of medical event definitions (i.e., one for permanent implant therapy vs. all others). Whereas most medical events have a manageable target dose assessment mechanisms, permanent implant therapy does not lend itself to a clearly dose based evaluation system to determine if an event occurred. For an implant treatment evaluation there should be common elements of a pre-approved treatment plan, attestation by the attending oncologist that the plan was completed in surgery as intended and a post implant follow**

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up that confirms by imaging that the implantation was not grossly flawed that lead to a clinically significant effect (diminished function of an organ). A revised definition of Medical Event should still capture doses to unintended organs associated with permanent implants that exceed the parameters defined by the physician in the written directive (e.g., dose to rectum/dose to urethra/dose to bladder).

The Agency is also very interested in the ongoing discussion regarding medical events, attestations, grandfathering and assistant RSOs. Please keep us apprised of these developments.

Regards,

Gibb

C. Gibb Vinson
Head of Radioactive Materials
Illinois Emergency Management Agency
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Please visit the nuclear safety section of the Agency's website at www.iema.illinois.gov/iema/dns.asp for the latest information concerning the Division of Nuclear Safety's programs. Our website includes important information such as new and proposed requirements, guidance, events and other pertinent items of interest.

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From: Donald L. Saah [mailto:donald.saah@nrc.gov]
Sent: Friday, May 20, 2011 3:11 PM
To: Vinson, Gibb
Subject: FSME-11-044 - Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations

The subject line letter, FSME-11-044, is contained in the attached electronic file, and can be found at the FSME website: http://nrc-stp.ornl.gov/.

Thank you.

May 20, 2011

ALL AGREEMENT STATES, MICHIGAN
STATE LIAISON OFFICERS

OPPORTUNITY TO COMMENT ON PRELIMINARY PROPOSED RULE LANGUAGE FOR MEDICAL USE REGULATIONS (FSME-11-044)

Purpose: The Nuclear Regulatory Commission (NRC or Commission) is making available for comment preliminary proposed rule language concerning the NRC's proposed amendments to the medical use regulations.

Background: The NRC plans to amend Part 35 to Title 10 of the *Code of Federal Regulations* (10 CFR). These proposed amendments include lowering the paperwork burden for certain license applications, clarifying certain training and experience (T&E) requirements for authorized users, expanding the ability of licensees to use sealed sources and devices approved in the Sealed Source and Device Registry, expanding and clarifying requirements for parenteral administration of alpha emitters, and other minor changes. In addition, NRC staff is considering several other revisions (e.g. medical event definition, attestation requirements, extending grandfathering to certain certified individuals, assistant/associate radiation safety officers, and increased frequency of molybdenum breakthrough testing and reporting). The proposed rule language for these issues will be developed after NRC staff has conducted two public workshops scheduled for June 20-21, 2011 in New York, New York, and in August 2011, in Houston, Texas. Public input at these workshops will help inform the development of the proposed rule.

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*This information request has been approved by OMB 3150-0029 expiration 11/30/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

*This information request has been approved by OMB 3150-0163, expiration 01/31/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0163), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Discussion: The NRC is making the preliminary proposed rule language for the items summarized above available to inform stakeholders of the current status of this proposed rulemaking, and is inviting comment on the language. This preliminary proposed rule language may be subject to significant revisions during the rulemaking process. Stakeholder input at this stage will help inform the development of the proposed rule. The NRC will review and consider any comments received; however, the NRC will not respond to any comments received at this pre-rulemaking stage. As appropriate, the proposed rule will briefly discuss any substantive changes made to the preliminary language as a result of the comments now being solicited. Stakeholders will have a further opportunity to comment on the rule language when it is published as a proposed rule in accordance with the provisions of the Administrative Procedures Act. The NRC will respond to any such comments in the Statements of Consideration published with the final rule language. The preliminary proposed rule language can be viewed and downloaded electronically via the Federal Rulemaking Web site at http://www.regulations.gov by searching for Docket ID NRC-2008-0175 as well as in the Agencywide Documents Access and Management System (ADAMS) Accession Number ML111390420. After the Commission has reviewed and approved the proposed rule, it will be formally published for comment. The notice announcing the availability of the preliminary proposed rule language and the public workshops was published in the *Federal Register* (76 FR 29171) on May 20, 2011, and can be viewed and downloaded electronically at http://www.gpo.gov/fdsys/pkg/FR-2011-05-20/pdf/2011-12048.pdf. The public comment period ends on September 15, 2011.

If you have any questions regarding this correspondence, please contact me at (301) 415-7278 or the individual named below.

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D. White, FSME/MSSA

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