



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

(FSME-11-044, May, Program, 10 CFR 35, Medical Use)

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](mailto: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](mailto: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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