



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

(FSME-14-078, August, Program, 10 CFR Parts 30, 32, and 35)

August 15, 2014

ALL AGREEMENT AND NON-AGREEMENT STATES
STATE LIAISON OFFICERS

OPPORTUNITY TO COMMENT ON PROPOSED AMENDMENTS TO MEDICAL USE OF
BYPRODUCT MATERIAL REGULATIONS, 10 CFR PARTS 30, 32 AND 35 AND
NOTIFICATION OF OCTOBER 8, 2014 PUBLIC MEETING (FSME-14-078)

Purpose: To notify the Agreement States that a proposed rule entitled “Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments” was published in the *Federal Register* (FR) for public comment. A notice of availability of the draft guidance to go with the proposed changes was also published in the FR for public comment. The U.S. Nuclear Regulatory Commission (NRC) is also hosting a public meeting on October 8, 2014, to discuss the proposed rule and associated regulatory guidance.

Background: The NRC is proposing to amend Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) related to the medical use of byproduct material. First, this rule proposes amendments to the reporting and notification requirements for a medical event for permanent implant brachytherapy. Second, the rule proposes changes to the training and experience (T&E) requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists; to the requirements for measuring molybdenum (Mo) contamination and reporting of failed technetium and rubidium generators; and to allow Associate Radiation Safety Officers to be named on a medical license. Third, the rule proposes changes to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., “grandfather” these individuals) so that they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the prior T&E requirements.

The proposed rule was published in the FR (79 FR 42410) on July 21, 2014. The rule is posted on the Federal eRulemaking Portal at: <http://www.regulations.gov> under Docket No. NRC-2008-0175. On July 21, 2014, NRC also published a notice of availability of the draft guidance to go with these proposed changes (79 FR 42224) in the FR. The notice of availability of the draft guidance is also posted on the Federal eRulemaking Portal at: <http://www.regulations.gov> under Docket No. NRC-2014-0030.

Discussion: **Comments for both the proposed rule and the conforming guidance documents should be submitted by November 18, 2014.** Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before the due dates.

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the FR on September 3, 1997, (62 FR 46517), this rule involves regulations that have been assigned compatibility category "B," "C," "D," and "H&S". Section-specific compatibility designations are found in the "Agreement State Compatibility" section of the *Federal Register* notice (FRN). As stated in the FRN for the proposed rule, the NRC is seeking specific input whether the compatibility designation of medical event reporting should be changed from the current compatibility designation C to compatibility B.

The State Liaison Officers should note that an Environmental Assessment (EA) has been prepared in support of the proposed rule. The conclusion of the EA is that no significant environmental impact will result from the proposed rule. The EA is available in NRC's Agencywide Documents Access and Management System (ADAMS) under Accession No. ML14184A621. If you have any comments on the rule and its environmental impact, please send them by November 18, 2014.

The NRC staff plans to hold a public meeting to promote understanding of the proposed amendments and to facilitate public comments. The public meeting is tentatively scheduled for October 8, 2014, from 9:00 a.m. to 4:00 p.m. (Eastern Standard Time), at the NRC White Flint Complex, 11555 Rockville Pike, Rockville, MD. You will also be able to participate via webinar and teleconference. The public meeting will be posted on the NRC's public meeting Web site at least 10 calendar days before the meeting. You may also monitor the NRC's public meeting Web site for additional information about the meeting at: <http://www.nrc.gov/public-involve/public-meetings/index.cfm>.

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

POINT OF CONTACT: Neelam Bhalla
TELEPHONE: 301-415-0978

INTERNET: Neelam.Bhalla@nrc.gov
FAX: 301-415-5955

/RA/

Christopher G. Miller, Director
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs