

June 24, 2009

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Mark R. Shaffer, Director
Division of Intergovernmental Liaison
and Rulemaking **/RA/**
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: DIRECT FINAL RULE TO AMEND 10 CFR PART 35 "MEDICAL
USE OF BYPRODUCT MATERIAL – AUTHORIZED USER
CLARIFICATION"

Enclosed for your signature is a direct final rule with the companion proposed rule (Enclosures 1 and 2) amending U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 35, Medical Use of Byproduct Material. This rule amends several sections in 10 CFR Part 35 to clarify that individuals who do not need to comply with the training requirements under § 35.57 may serve as preceptors and work experience supervisors for individuals seeking recognition on an NRC license for the same uses. Additionally, several minor administrative changes are included in this rulemaking. The direct final rule approach was used because the clarifications and administrative changes are considered to be noncontroversial.

The direct final rule supports NRC's 2008-2013 Strategic Plan in the areas of safety and operational excellence. In the area of safety, the proposed rule supports the NRC Safety Goal (develop, maintain, and implement licensing and regulatory programs for materials users to ensure the adequate protection of health and safety) by facilitating the ability of medical licensees to have an adequate number of authorized individuals to provide necessary medical treatment to patients.

In the area of operational excellence, the proposed rule supports the objective of openness. Specifically, input to address issues within the proposed rule was solicited from the Advisory Committee on the Medical Use of Isotopes during a public meeting held in October 2008. This supports the agency's openness strategy 3 (providing for fair, timely, and meaningful stakeholder involvement in NRC decision making), and strategy 5 (initiating early communication with stakeholder on issues of substantial interest).

Notices: Enclosure 3 (EDO Daily Note) documents that the Executive Director for Operations (EDO) intends to sign the Federal Register Notice. Enclosure 4 ("Notice of Final Rule Signed by the EDO") and Enclosure 5 ("Weekly Report to the Commission") each document that the EDO has signed the two *Federal Register* Notices. The Approved for Publication can be found in Enclosure 6 of this paper. The appropriate Congressional committees will be notified.

CONTACT: Edward M. Lohr, FSME/DILR
(301) 415-0253

Resources: No additional resources will be needed to implement this rule.

Coordination: The Offices of Administration, Enforcement, and Information Services concur with these amendments. The Office of the General Counsel has no legal objection. The Office of the Chief Financial Officer has reviewed the proposed rule for resource implications and has no objection. The Office of Public Affairs is not issuing a press release.

Enclosures:

1. *Federal Register* Notice of Direct Final Rule
2. *Federal Register* Notice of Proposed Rule
3. EDO Daily Note
4. Notice of Final Rule Signed by EDO
5. Weekly Report
6. Approved for Publication
7. CRA Forms

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