

December 1, 2010

ALL AGREEMENT STATES, MICHIGAN

OPPORTUNITY TO COMMENT ON THE USE OF ELECTRONIC SIGNATURES FOR U.S. NUCLEAR REGULATORY COMMISSION DOCUMENTS RELATED TO THE MEDICAL USE OF BYPRODUCT MATERIAL MAINTAINED AT LICENSEES' FACILITIES (FSME-10-094)

**Purpose:** To notify the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) published a *Federal Register* Notice (FRN) on October 20, 2010 (75 FR 64749), to solicit public input on the use of electronic signatures for NRC documents related to the medical use of byproduct material maintained at licensees' facilities.

**Background:** In connection with the American Recovery and Reinvestment Act and the Patient Protection and Affordable Care Act, the NRC is soliciting early public input on issues associated with the use of electronic signatures on documents related to the medical use of byproduct material that are not submitted to the NRC, but are maintained and inspected at the licensee's facility (i.e., written directives required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40 and records for inspection required by 10 CFR Part 35, subpart L). For medical use licensees, 10 CFR 35.5 permits the use of electronic media to produce and store records that are maintained and inspected at the licensee's site. The NRC is aware that many medical licensees already develop and store certain documents in electronic form and may use electronic signatures for electronic documents that require signatures by specific individuals. The NRC believes that electronic signatures should serve the same function as written signatures.

**Discussion:** Enclosed for your review and comment is the FRN (75 FR 64749), "Request for Comments on the Use of Electronic Signatures for NRC Documents Related to the Medical Use of Byproduct Material Maintained at Licensees' Facilities." The FRN provides questions about issues related to the implementation of electronic signatures, but are not conclusive, nor complete. The questions serve as an initial point for comments. Information is also posted at <http://www.regulations.gov> under Docket ID NRC-2010-0330. **We would appreciate receiving your comments by February 17, 2011.**<sup>1</sup>

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<sup>1</sup> 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.

FSME-10-094

-2-

If you have any questions regarding this communication, please contact me at 301-415-3340, or the individual named below.

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**/RA/ by Christian Einberg**

Robert J. Lewis, Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
*Federal Register* Notice

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-2-

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