



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

(FSME-07-110, December, Program, Radiopharmacy)

December 12, 2007

ALL AGREEMENT AND NON-AGREEMENT STATES STATE LIAISON OFFICERS

**PUBLICATION OF NRC GUIDANCE ABOUT COMMERCIAL RADIOPHARMACY LICENSES  
(FSME-07-110)**

Purpose: To inform the States that NUREG-1556, Volume 13, Revision 1, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses*, has been published and provides guidance about commercial radiopharmacy licenses.

Background: As described in previous communications, the U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally-occurring radioactive material (collectively known as NARM), as required by the Energy Policy Act of 2005 (EPA), which was signed into law on August 8, 2005. The rulemaking for this activity was noticed in the *Federal Register* (72 FR 55864) on October 1, 2007.

The new regulations for the expanded definition of byproduct material require new guidance and resulted in a revision to: (1) NUREG-1556, Volume 13, Revision 1; (2) NUREG-1556, Volume 9, Revision 2, *Program-Specific Guidance About Medical Use Licenses*. Additionally, a new NUREG-1556 volume was created, NUREG-1556, Volume 21, *Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator*. Volume 21 provides guidance about possession licenses for production of radioactive material using an accelerator. The guidance documents were developed with State input and take advantage of State expertise in the licensing of NARM and Ra-226.

Volume 13, Revision 1, was noticed in the *Federal Register* on July 3, 2007 (72 FR 36526) for a 30-day public comment period which ended August 2, 2007. The final report of Volume 13, Revision 1, may be found in NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/> or the "NARM Toolbox" at <http://nrc-stp.ornl.gov/narmtoolbox.html>. NUREG-1556, Volume 21, was finalized and published in October 2007. NUREG-1556, Volume 9, Rev. 2, will be finalized in the near future.

Discussion: The guidance volumes were developed by a joint NRC - State working group. After receiving comments from the States and the general public, NRC prepared a final version of Volume 13, Revision 1. The Agreement States may use these NUREG volumes as a basis for their regulatory guidance, as desired.

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

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