

February 8, 2008

ALL AGREEMENT AND NON-AGREEMENT STATES
STATE LIAISON OFFICERS

**PUBLICATION OF NUCLEAR REGULATORY COMMISSION GUIDANCE ON MEDICAL USE
LICENSES (FSME-08-018)**

Purpose: To inform the States that NUREG-1556, Volume 9, Revision 2, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses*, has been published. Volume 9 provides guidance about medical use 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 (EPAAct), 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, *Program-Specific Guidance About Commercial Radiopharmacy Licenses*, and (2) NUREG-1556, Volume 9, Revision 2, *Program Specific Guidance About Medical Use Licenses*. A new NUREG-1556 volume, Volume 21, was developed to address 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 9, Rev. 2, was noticed in the *Federal Register* on August 2, 2007 (72 FR 42442) for a 30-day public comment period which ended September 4, 2007. The final report of Volume 9, Rev. 2, may be found initially on the "NARM Toolbox" at <http://nrc-stp.ornl.gov/narmtoolbox.html>. It will subsequently be posted on NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. NUREG-1556, Volume 21 and Volume 13, Rev. 1, were previously finalized and published in October and November 2007, respectively.

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 9, Rev. 2. The Agreement States may use these NUREG volumes as a basis for their regulatory guidance, as desired.

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