[7590-01-P]

NUCLEAR REGULATORY COMMISSION

NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use Licenses"

Draft Guidance Document for Comment

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability for public comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) has amended its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of byproduct material to include these radioactive materials. Subsequently, these radioactive materials were placed under NRC's regulatory authority. NRC is revising its regulations to provide a regulatory framework that includes these newly added radioactive materials. See SECY-07-0062, "Final Rule: Requirements for Expanded Definition of Byproduct Material," dated April 3, 2007, for information on that rulemaking.

Two licensing guidance documents in the NUREG-1556 series are being revised along with these new regulations to provide guidance related to the new requirements:
(1) NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Commercial Radiopharmacy Licenses," and
(2) NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses – Program Specific Guidance About Medical Use Licenses." A new volume in the NUREG-1556 series has also been developed to address the production of radioactive material using an

accelerator. This NUREG is entitled "NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

This notice is announcing the availability of one of these three licensing guidance documents for public comment: NUREG-1556, Volume 9, Revision 2. The other two NUREGs were previously noticed for public comment: (1) NUREG-1556, Volume 13, Revision 1, on July 3, 2007 (72 FR 36526), and (2) NUREG-1556, Volume 21, on May 29, 2007 (72 FR 29555).

DATES: Please submit comments on NUREG-1556, Volume 9, Revision 2, by **[insert 30 days from date of publication]**. Comments received after this date will be considered if practical to do so, but the NRC staff is able to ensure consideration only for those comments received on or before this date.

ADDRESSES: NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Medical Use Licenses," Draft Report for Comment, is available for inspection and copying for a fee at the NRC's Public Document Room (PDR), Public File Area O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of the NRC's public documents. The ADAMS Accession Number for NUREG-1556, Volume 9, Revision 2, is ML071860070. If you do not have access to ADAMS or

if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov.

The document will also be posted on NRC's public Website at:

(1) http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/ on the "Consolidated Guidance About Materials Licenses (NUREG-1556)" Website page, and

(2) http://www.nrc.gov/reading-rm/doc-collections/nuregs/docs4comment.html on the "Draft NUREG Series Publications for Comment." It will also be posted on the Office of Federal and State Materials and Environmental Management Programs' NARM (Naturally-Occurring and Accelerator-Produced Radioactive Material) Toolbox Website page at: http://nrc-stp.ornl.gov/narmtoolbox.html under the heading of "Licensing Guidance."

A free single copy, to the extent of supply, may be requested by writing to the Office of the Chief Information Officer, Reproduction and Distribution Services, U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555-0001; facsimile: 301-415-2289; e-mail: Distribution@nrc.gov.

Please submit comments to Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001. You may also deliver comments to 11545 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:30 p.m. Federal workdays, or by e-mail to: nrcrep@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Torre Taylor, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7900, e-mail: tmt@nrc.gov.

SUPPLEMENTARY INFORMATION

BACKGROUND

On August 8, 2005, the President signed into law the EPAct. Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material as defined in Section 11e. of the Atomic Energy Act of 1954 (AEA), placing additional byproduct material under the NRC's jurisdiction, and required the Commission to provide a regulatory framework for licensing and regulating this additional byproduct material.

Specifically, Section 651(e) of the EPAct expanded the definition of byproduct material by: (1) adding any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); and (2) adding any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of the Department of Energy, the Secretary of the Department of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity (Section 11e.(4) of the AEA).

NRC is revising its regulations to provide a regulatory framework that includes these

newly added radioactive materials. See SECY-07-0062, "Final Rule: Requirements for Expanded Definition of Byproduct Material," dated April 3, 2007, for information on that rulemaking.

DISCUSSION

As part of the rulemaking effort to address the mandate of the EPAct, the NRC also evaluated the need to revise certain licensing guidance documents to provide necessary guidance to applicants in preparing license applications to include the use of the newly added radioactive material as byproduct material. Two NUREG-1556 documents are being revised to provide additional guidance to licensees: (1) NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Commercial Radiopharmacy Licenses," and (2) NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Medical Use Licenses." Additionally, a new NUREG-1556 volume has been developed as Volume 21 to address production of radioactive material using an accelerator. This NUREG-1556, Volume 21, is entitled: "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

At this time, NRC is announcing the availability for public comment NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Medical Use Licenses," Draft Report for Comment. The other two NUREGs were previously noticed for public comment: (1) NUREG-1556, Volume 13, Revision 1, on July 3, 2007 (72 FR 36526) and (2) NUREG-1556, Volume 21, on May 29, 2007 (72 FR 29555).

NUREG-1556, Volume 9, Revision 2, “Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Medical Use Licenses,” provides guidance for applicants in preparing their license applications for the medical use of byproduct material. Volume 9 is being revised primarily to provide additional guidance related to the NARM rule, as discussed above.

In the draft final rule for the NARM rulemaking, the concept of consortiums and noncommercial distribution was addressed. In summary, because of the short-lived radionuclides associated with Positron Emission Tomography (PET), the source of these radioactive materials needs to be produced in the facility of use or within close proximity. The NRC developed a new regulatory process based on existing practices for consortiums and noncommercial distribution. For this purpose, educational institutions, medical use facilities or Federal facilities may form consortiums with adjacent or nearby hospitals to jointly own or share in the operation and maintenance costs of the PET radionuclide production facility. This is discussed in more detail in SECY-07-0062, “Final Rule: Requirements for Expanded Definition of Byproduct Material,” dated April 3, 2007, and within the draft *Federal Register* notice that is provided as an attachment to SECY-07-0062.

NUREG-1556, Volume 9, Revision 2, provides guidance for applicants in licensees about consortiums and noncommercial distribution in Sections 1 and 8, and in Appendix AA. NRC is requesting specific comments on this guidance to ensure that it is clear and easily understood by affected stakeholders.

It is also being revised to clarify training and experience requirements, replaces NRC Form 313A with six new NRC Form 313A forms specific to types of authorizations. References and information related to Subpart J of 10 CFR Part 35 have been removed since these regulatory requirements expired on October 25, 2005.

Additionally, other minor changes are being made that are administrative in nature, such as updating the Agreement State section and updating references. Also, information related to identifying and protecting sensitive information is being updated.

NRC is only requesting comments on the specific changes in this document related to those revisions discussed above. NRC will make corrections if any errors or editorial corrections are noted; however, any comments not related to these specific changes will be evaluated during the next routine review of NUREG-1556, Volume 9.

Dated at Rockville, Maryland, this 26th day of July, 2007.

For the Nuclear Regulatory Commission.

/RA/

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Dennis K. Rathbun, Director
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs

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