

NUCLEAR REGULATORY COMMISSION

NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses
Program-Specific Guidance About Possession Licenses for Production
of Radioactive Material Using an Accelerator"

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability

SUMMARY: The Nuclear Regulatory Commission (NRC) is announcing the completion and availability of NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," dated October 2007.

ADDRESSES: Copies of NUREG-1556, Volume 21, may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328; www.access.gpo.gov/su_docs; 202-512-1800 or The National Technical Information Service, Springfield, Virginia 22161-0002; www.ntis.gov; 1-800-533-6847 or, locally, 703-805-6000.

A copy of the document is also available for inspection and/or copying for a fee in the NRC Public Document Room, 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 21 is ML072900058. 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: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/> on the "Consolidated Guidance About Materials Licenses (NUREG-1556)" Website page, and 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." Some publications in the NUREG series that are posted at NRC's Web site address www.nrc.gov are updated regularly and may differ from the last printed version.

A free single copy, to the extent of supply, may be requested by writing to 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.

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; or Duane White, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6272, email: dew2@nrc.gov.

SUPPLEMENTARY INFORMATION:

On August 8, 2005, the President signed into law the Energy Policy Act of 2005 (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 these additional byproduct materials.

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 (EPA), the Secretary of the Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), 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 revised its regulations to provide a regulatory framework that includes these newly added radioactive materials. See *Federal Register* notice 72 FR 55864, dated October 1, 2007. As part of the rulemaking effort to address the mandate of the EPAcT, the NRC also evaluated

the need to revise certain licensing guidance to provide necessary guidance to applicants in preparing license applications to include the use of the newly added radioactive materials 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 was developed to address production of radioactive material using an accelerator. This NUREG-1556 volume is entitled: Volume 21, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" was noticed for public comment on May 29, 2007 (72 FR 29555). Six comment letters were received and these comments were considered by the staff as this NUREG was finalized.

NUREG-1556, Volume 21, provides guidance on preparing a license application for the production of radioactive material using an accelerator(s). It also includes the criteria that NRC staff will use in evaluating license applications for this use. This document includes guidance that is specific to the activities that take place once radioactive materials are produced by the accelerator, which include material in the target and associated activation products. This document does not include information for the operation of the accelerator as NRC does not regulate the accelerator or its operation.

Volume 21 provides guidance related to each of the items that applicants should address in their materials license application, which includes items such as radioactive material

that will be produced and its purpose; information on individuals responsible for the radiation safety program; training for individuals that will handle radioactive material; description of the facilities and equipment used; and the radiation safety program. There are some aspects of producing radioactive materials using an accelerator that are unique to this type of use and are discussed in the document. Some examples include training and experience for individuals who will handle radioactive material during the maintenance and repair of the accelerator and other associated equipment, and guidance on the facility design and type of equipment needed to transfer and handle large radioactive materials with high activities. This document also includes guidance on the production and noncommercial distribution of positron emission tomography radioactive drugs to consortium members.

The remaining two NUREG-1556 volumes were noticed separately: (1) NUREG-1556, Volume 13, Revision 1, on July 3, 2007 (72 FR 36526), and (2) NUREG-1556, Volume 9, Revision 2, on August 2, 2007 (72 FR 42442). These two NUREGs are being finalized and will be available in the near future.

Dated at Rockville, Maryland, this 1st day of November 2007.

For the Nuclear Regulatory Commission.

/RA/

Patrice M. Bubar, Deputy Director
Division of Intergovernmental Liaison
and Rulemaking,
Office of Federal and State Materials
and Environmental Management Programs

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