

NUCLEAR REGULATORY COMMISSION

[NRC-2016-0190]

Program-Specific Guidance About Commercial Radiopharmacy Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: NUREG; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 2 to NUREG-1556, Volume 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." Volume 13 of NUREG-1556 has been revised to include information on updated regulatory requirements, safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices consistent with current regulations. This volume is intended for use by applicants, licensees, and the NRC staff.

DATE: NUREG-1556, Volume 13, Revision 2, was published in March 2019.

ADDRESSES: Please refer to Docket ID **NRC 2016-0190**, when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2016-0190**. Address questions about NRC Docket IDs in [regulations.gov](http://www.regulations.gov) to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the

FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public

Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. NUREG-1556, Volumes 13, Revision 2, is located at ADAMS Accession Number ML18180A187. This document is also available on the NRC's public Web site at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/> under "Consolidated Guidance About Materials Licenses (NUREG-1556)."

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Anthony McMurtray, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2746; e-mail: Anthony.McMurtray@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC issued a revision to NUREG-1556, Volumes 13, to provide guidance to existing materials licensees covered under commercial radiopharmacy licenses and to applicants preparing an application for a commercial radiopharmacy license. This NUREG volume also provides the NRC staff with criteria for evaluating commercial radiopharmacy license applications. The purpose of this notice is to notify the public that the NUREG-1556 volume listed in this document was issued as a final report.

II. Additional Information

The NRC published a notice of the availability of the draft report for comment version of NUREG-1556, Volume 13, Revision 2 in the *Federal Register* on

January 24, 2017 (82 FR 8227), with a public comment period of 59 days. The public comment period closed on March 24, 2017. Public comments and the NRC staff responses to the public comments for NUREG-1556, Volume 13, Revision 2 are available in ADAMS under Accession No. ML18305B303.

III. Congressional Review Act

This NUREG volume is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found this NUREG revision to be a major rule as defined in the Congressional Review Act.

Dated at Rockville, Maryland, this 2nd day of May, 2019.

For the Nuclear Regulatory Commission.

/RA/

Andrea L. Kock, Director,
Division of Materials Safety, Security, State
and Tribal Programs,
Office of Nuclear Material Safety and
Safeguards.

SUBJECT: ISSUANCE OF REVISION 2 TO NUREG-1556 (CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES), VOLUME 13 (PROGRAM-SPECIFIC GUIDANCE ABOUT COMMERCIAL RADIOPHARMACY LICENSES) DATED, MAY 2, 2019.

ADAMS Accession No.: ML19109A223

***concurrence via e-mail**

OFC	NMSS/MSTB	NMSS/MSTB	OGC NLO*	NMSS/MSST
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DATE	4/22/19	4/22/19	4/24/19	5/2/19

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