

May 13, 2009

EGM-09-004

MEMORANDUM TO: Samuel J. Collins, Regional Administrator, Region I
Luis A. Reyes, Regional Administrator, Region II
Mark Satorius, Regional Administrator, Region III
Elmo E. Collins, Regional Administrator, Region IV
Eric J. Leeds, Director, Office of Nuclear Reactor Regulation
Michael R. Johnson, Director, Office of New Reactors
Charles L. Miller, Director, Office of Federal and State Materials and
Environmental Management Programs
Michael F. Weber, Director, Office of Nuclear Material Safety and
Safeguards
Roy P. Zimmerman, Director, Office of Nuclear Security
and Incident Response

FROM: Cynthia A. Carpenter, Director
Office of Enforcement/RA/

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - INTERIM GUIDANCE
FOR DISPOSITIONING VIOLATIONS OF NATURALLY OCCURRING
AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS
(NARM) REQUIREMENTS

Purpose:

The purpose of this memorandum is to provide guidance for dispositioning inspection findings related to a licensee's implementation of naturally occurring and accelerator-produced radioactive materials (NARM) requirements.

Background:

Prior to the enactment of the Energy Policy Act of 2005 (EPAAct), on August 8, 2005, naturally occurring and accelerator-produced radioactive materials (NARM) were not covered under the Atomic Energy Act of 1954, and therefore, were not regulated by the NRC. Most of these materials were regulated by State regulatory authorities.

Although the legislation made NRC's authority over these new materials effective immediately when the bill was enacted in August 2005, the NRC did not have regulations in place that would specifically apply to this newly covered byproduct material. The NRC issued a time-limited waiver on August 31, 2005 (70 FR 51581), for continued use and possession of NARM, allowing time for the NRC to develop regulations to implement the new requirements.

Contact Leelavathi Sreenivas, OE
(301)415-1285

The NRC published notification of its plan for the transition of regulatory authority resulting from the expanded definition of byproduct material in the *Federal Register* on October 1, 2007 (72 FR 55864). This followed publication of a final rule covering the new byproduct materials on October 1, 2007 (72 FR 55863). The regulations set forth in that rule became effective on November 30, 2007, for some licensees and later for others. Accordingly, the transition plan set forth the applicable dates for waiver terminations.

On October 4, 2007, the NRC issued Regulatory Information Summary (RIS) 2007-22 informing recipients of the recent issuance of regulations concerning the new byproduct materials. The RIS notified recipients that the Commission would be terminating waivers in phases, beginning November 30, 2007, and ending August 7, 2009. The RIS explained that upon waiver termination, all persons in possession of material newly defined as byproduct material in specified States, U.S. Territories or areas of exclusive federal jurisdiction would be expected to be in compliance with NRC regulations. In addition, the RIS identified that such persons would be required to (1) submit license amendment requests for NARM within 6 months from the date the waiver is terminated if they hold an NRC specific byproduct materials license, or (2) submit a license application for NARM within 12 months from the date the waiver is terminated.

The RIS also explained that some of the newly defined byproduct materials may already be covered by existing NRC licenses, since the new definition included NARM material. Therefore, recipients were asked to review their license and contact the NRC regional office with questions about whether a license amendment was necessary. For materials regulated as generally licensed devices, the RIS stated that upon waiver termination, it would be necessary to follow registration and /or reporting requirements in the new regulations. Users of the new byproduct materials in Agreement States were advised to contact the State regulatory agency for questions related to regulation of the materials.

Upon receipt of either a license amendment request or a new license application, the respective NRC regional office will notify the applicant of its receipt of the request. The notification will document that the applicant complied with this aspect of the regulations. In cases where the currently held license had been broadly written such that no license amendment was required to encompass the NARM isotopes and locations of use, licensees are required to include all existing NARM activities with the existing byproduct material licensed activities and meet all the existing commitments of the current license.

Notwithstanding the issuance of the *Federal Register* notice and the RIS, it is recognized that some entities (in particular, entities who solely possess radium) may not know about NRC's new requirements. Customers of manufacturers and distributors (M&Ds) still supporting radium devices could have been made aware of the new requirements, as NRC has conducted extensive outreach to M&Ds. However, entities who possess radium devices that are no longer manufactured and/or supported by M&Ds, may not be aware of the new requirements or know they are required to apply for licensee status.

A small number of NRC licensees missed the dates for submitting a license amendment request, and self-reported. It is reasonable to believe that there will be additional instances of such errors identified in the future.

Disposition of Violations of NARM Requirements:

If an inspector identifies a potential noncompliance with a licensee's implementation of the NARM requirements, he or she should notify the applicable Regional Branch Chief before conducting the exit meeting with the licensee. All potential noncompliances of NARM requirements shall be brought back to the applicable Regional Office for disposition.

The Regional Office will evaluate each potential noncompliance and make one of two conclusions as discussed below. Discretion can be considered both for failure to initially apply for or amend a license, as well as violations in the implementation of the requirements. The direction below also applies to an applicant.

1. Use of ENFORCEMENT DISCRETION to not issue a violation for failure either: (1) to submit a license application or amendment request to include NARM activities; or (2) in cases where the license had been broadly written such that no license amendment was required to encompass the NARM isotopes and locations of use, to include all existing NARM activities with the existing byproduct material licensed activities.

If this is the licensee's or permittee's first occurrence after the effective date of the NARM requirements (waiver termination date), the Regional Office may then consider using enforcement discretion and not issue a violation, if all four of the following conditions are met:

- a. The licensee's failure did not result in an actual safety, health, or security consequence;
- b. The licensee's failure was not willful;
- c. The licensee has provided a reasonable argument that they had reason to believe that the new requirement did not apply to them, or that they were unaware of the new requirement; and
- d. The licensee has committed to submit an initial license application within 60 days; or to submit a license amendment request within 30 days; or the licensee confirms that all existing NARM activities will be included with the existing byproduct material licensed activities and will meet all the existing commitments of the current license within 30 days.

NOTE: typically, the first day of the inspection will be the start date, and the inspection findings will be documented in the inspection record to describe the noncompliance(s), the licensee's corrective actions and the schedule for taking corrective actions. These cases will be issued an Enforcement Action (EA) number.

2. Use of NORMAL ENFORCEMENT process for NARM implementation violations

The Regional Office will use the normal enforcement process to evaluate the non-compliance, if the licensee has not met the conditions listed above. Typically, citing a severity level IV will be appropriate with a consideration of escalated enforcement for willfulness or any safety significant issues.

This EGM will be in effect until further notice.

The Regional Office will evaluate each potential noncompliance and make one of two conclusions as discussed below. Discretion can be considered both for failure to initially apply for or amend a license, as well as violations in the implementation of the requirements. The direction below also applies to an applicant.

1. Use of ENFORCEMENT DISCRETION to not issue a violation for failure either: (1) to submit a license application or amendment request to include NARM activities; or (2) in cases where the license had been broadly written such that no license amendment was required to encompass the NARM isotopes and locations of use, to include all existing NARM activities with the existing byproduct material licensed activities.

If this is the licensee's or permittee's first occurrence after the effective date of the NARM requirements (waiver termination date), the Regional Office may then consider using enforcement discretion and not issue a violation, if all four of the following conditions are met:

- a. The licensee's failure did not result in an actual safety, health, or security consequence;
- b. The licensee's failure was not willful;
- c. The licensee has provided a reasonable argument that they had reason to believe that the new requirement did not apply to them, or that they were unaware of the new requirement; and
- d. The licensee has committed to submit an initial license application within 60 days; or to submit a license amendment request within 30 days; or the licensee confirms that all existing NARM activities will be included with the existing byproduct material licensed activities and will meet all the existing commitments of the current license within 30 days.

NOTE: typically, the first day of the inspection will be the start date, and the inspection findings will be documented in the inspection record to describe the noncompliance(s), the licensee's corrective actions and the schedule for taking corrective actions. These cases will be issued an Enforcement Action (EA) number.

2. Use of NORMAL ENFORCEMENT process for NARM implementation violations

The Regional Office will use the normal enforcement process to evaluate the non-compliance, if the licensee has not met the conditions listed above. Typically, citing a severity level IV will be appropriate with a consideration of escalated enforcement for willfulness or any safety significant issues.

This EGM will be in effect until further notice.

Electronic DISTRIBUTION:

OE r/f OE-Web (3 days after issuance)
EGM File Binder OE staff RidsEDOMailCenter, Reg. Enf.Coordinators,FSME
X PUBLIC X NON-SENSITIVE **ML091340060**

OFFICE	ES:OE	FSME	R-I	R-III	R-IV
NAME	LSreenivas	JLeuhman	MMcLaughlin	JHeck	CMaier for MHaire
DATE	4/15/2009	4/ 29/2009	4/15/2009	4/15/2009	4/15/2009
OFFICE	OGC	OE: BC	OE: DD	OE:D	
NAME	LClark	NHilton	SMagruder	CCarpenter	
DATE	4/17/2009	5/07/2009	5/12/2009	5/13/2009	

OFFICIAL RECORD COPY