April 18, 2013

EGM-13-003

MEMORANDUM TO: William M. Dean, Regional Administrator, Region I
Victor M. McCree, Regional Administrator, Region II
Charles A. Casto, Regional Administrator, Region III
Arthur A. Howell, Regional Administrator, Region IV
Eric J. Leeds, Director, Office of Nuclear Reactor Regulation
Glenn M. Tracy, Director, Office of New Reactors
Mark A. Satorius, Director, Office of Federal and State Materials and Environmental Management Programs
Catherine Haney, Director, Office of Nuclear Material Safety and Safeguards
James T. Wiggins, Director, Office of Nuclear Security and Incident Response

FROM: Roy P. Zimmerman, Director ***/RA/***
Office of Enforcement

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - INTERIM GUIDANCE FOR DISPOSITIONING VIOLATIONS INVOLVING 10 CFR 35.60 AND 10 CFR 35.63 FOR THE CALIBRATION OF INSTRUMENTATION TO MEASURE THE ACTIVITY OF RUBIDIUM-82 AND THE DETERMINATION OF RUBIDIUM-82 PATIENT DOSAGES

Purpose:

The purpose of this memorandum is to provide guidance for dispositioning inspection findings related to a licensee's implementation of calibration requirements for rubidium-82 (Rb-82) activity measurement systems in accordance with 10 CFR 35.60; and the requirement to determine the Rb-82 dosage before medical use in accordance with 10 CFR 35.63.

Background:

Prior to the enactment of the Energy Policy Act of 2005 (EPAct), on August 8, 2005, naturally occurring and accelerator-produced radioactive materials (NARM) were not covered by the definition of byproduct material in Section 11e., of the Atomic Energy Act of 1954, and therefore, were not within NRC's jurisdictional purview. At the time, most of these materials were regulated by State regulatory authorities. Section 651(e) of the EPAct expanded the definition of byproduct material to cover such materials and, consequently, to place such materials within

CONTACT: Leelavathi Sreenivas, OE/EB
(301) 415-1285

the scope of NRC's regulatory jurisdiction. One such material is Rb-82. On October 1, 2007, the NRC published in the *Federal Register* (72 FR 55864) amendments to its regulations intended to address NARM.

Regarding the NRC's regulation of Rb-82, this Enforcement Guidance Memorandum (EGM) is intended to address two instances in which it is not possible to meet the current NRC regulatory requirements: (1) the medical use calibration requirements for the radiation detectors associated with Rb-82 generator systems and (2) the inability of users of those systems to determine the dosage of the Rb-82 before medical use. As discussed further, the short half-life (76 seconds) and the administration of the Rb-82 chloride, eluted directly from the generator system, into the patient preclude a licensee's measurement of the dosage in a dose calibrator prior to administration. A small number of NRC licensees use these devices, including those that used them prior to the implementation of the NARM rule in 2007.

Rb-82 generators are used to produce Rb-82 chloride, an imaging radiopharmaceutical. Its 76 second half-life and small total elution activities (30 to 100 millicuries of Rb-82) make its use for imaging significantly different from other imaging products currently regulated in 10 CFR Part 35, Subpart D, "Unsealed Byproduct Material - Written Directive Not Required." These differences were identified after a product recall in 2011 during a detailed examination of NRC's current regulations with respect to the operation of the generator, the infusion cart, the radiation detector used to measure the Rb-82 dosage, and the strontium-82/strontium-85 breakthrough determination process.

In particular, 10 CFR 35.60 requires a licensee to calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (*i.e.*, while liquids are flowing by the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible.

In addition, 10 CFR 35.63 requires a licensee to determine the activity of each dosage administered before medical use. Due to the 76 second half-life of Rb-82 and direct infusion into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration.

Disposition of Violations of 10 CFR 35.60 or 10 CFR 35.63 Requirements:

If an inspector identifies a potential noncompliance with a licensee's implementation of the requirements for Rb-82 generator systems, in accordance with 10 CFR 35.60 or 10 CFR 35.63, he or she should notify the appropriate Regional Branch Chief before conducting the exit meeting with the licensee. All potential non-compliances shall be brought back to the applicable Regional Office for disposition.

The Regional Office shall evaluate each potential noncompliance and make one of two conclusions, as discussed below:

1. Use of ENFORCEMENT DISCRETION to not issue a violation for failure to comply with requirements for Rb-82 generator systems, in accordance with 10 CFR 35.60 or 10 CFR 35.63, if all three of the following criteria are met:

   a) The licensee must have written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications. The licensee must perform the tests, at least every twelve months (and repeated after repair or replacement), and maintain records documenting the performance of and results of these tests. The radiation detector specifications are compared to the values obtained during tests of the detector's electronics and the response of the radiation response to a radiation source in the static mode. The licensee may use documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and radiation detector test.

      [Note: If in the future the manufacturer were to develop a calibration procedure (*i.e.*, accuracy, linearity and geometry evaluations of the detector), then such calibration must be performed for the detector as opposed to the electronic and radiation function tests, as currently used.]

   b) All authorized user(s) (AU) for medical uses under 10 CFR Part 35.200 who are using Rb-82 chloride, as well as the Radiation Safety Officer for that facility, must have successfully completed training specific to the manufacturer and model of generator and infusion cart being used.

      Such training must include: (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedures for the clinical use of Rb-82 chloride.

      Until the generator manufacturer develops static or dynamic calibration procedures for calibrating the radiation detector in the infusion cart, the quality control procedures must include: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer.

      This training requirement is met by satisfactory completion of a training program, which addresses all of these required topics, provided by the manufacturer. The licensee must maintain documentation that all AUs using Rb-82 and the RSO have satisfactorily completed such training.

   c) The licensee must record the activity of each dosage administered, as provided by the infusion cart.

If the regional office determines that the noncompliance meets the criteria for using discretion, the regional office can disposition the violation without a Headquarters enforcement panel. However, the violation shall be assigned an enforcement action (EA) number to document the exercise of enforcement discretion and use of this EGM. This discretion is not limited to the initial inspection identifying the non-compliance and can be applied to subsequent inspections provided that all the criteria continue to be met.

The following, or similar, language is to be included in the text of the inspection record or report discussing the inspection finding when exercising enforcement discretion in accordance with this EGM:

> "A violation of [insert as appropriate: 10 CFR 35.60 and/or 10 CFR 35.63] was identified during this inspection. In accordance with the Enforcement Policy, this violation would normally be categorized at Severity Level IV. However, in accordance with NRC Enforcement Guidance Memorandum (EGM) 13-003, issued April 18, 2013, the NRC is exercising enforcement discretion and not pursuing any enforcement action for this violation."

The letter to the licensee should include the following, or similar, language:

> "Although a violation of [insert as appropriate: 10 CFR 35.60 and/or 10 CFR 35.63] was identified and the issue was discussed during the exit meeting, [insert as appropriate: the licensee name or "your program"] met all of the criteria in EGM 13-003 for use of enforcement discretion, therefore NRC is exercising enforcement discretion and, will not issue any enforcement action for this violation."

2. Use of NORMAL ENFORCEMENT process.

The Regional Office will use the normal enforcement process in accordance with the current Enforcement Policy to evaluate and disposition the non-compliance, if the licensee is found not to have met the conditions listed above. Typically, citing a Severity Level IV violation would be appropriate with a consideration of escalated action for willfulness or any other safety significant issues.

This EGM will remain effective until the underlying technical issue is dispositioned through rulemaking or other regulatory action.

cc: M. Weber, DEDMRT
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