UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-13-048, May, Program, 10 CFR 35.60 and 35.63)

May 20, 2013

ALL AGREEMENT STATES

ISSUANCE OF 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 [EGM-13-003] (FSME-13-048)

Purpose: To inform the Agreement States of the U.S. Nuclear Regulatory Commission's (NRC) April 18, 2013, issuance of Enforcement Guidance Memorandum (EGM) EGM-13-003 concerning 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. The EGM is available at: http://pbadupws.nrc.gov/docs/ML1310/ML13101A318.pdf.

Background: NRC on October 1, 2007, published (in the *Federal Register* (72 FR 55864)) amendments to its regulations implementing portions of the Energy Policy Act of 2005 that gave NRC regulatory authority over naturally occurring and accelerator produced radioactive materials (NARM). One of the materials included in this new authority was the Rubidium-82/Strontium-82 (Sr-82) generators. In 2011, Bracco Diagnostics, Inc., CardioGen 82 Rb-82/ Sr-82 generators were voluntarily removed from the market by the manufacturer when it was discovered that a number of patients received Sr-82 and Sr-85 levels in excess of the breakthrough levels specified in NRC regulations.

After this product recall, NRC initiated a detailed examination of its 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 Sr-82/Sr-85 breakthrough determination process. As discussed in the EGM, it was determined that licensees using the generators could not meet the current NRC regulatory requirements in: (1) 10 CFR 35.60 to calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject in accordance with nationally recognized standards or calibration instructions provided by the manufacturer, and (2) 10 CFR 35.63 to determine the activity of each dosage administered before medical use. Without development of the EGM, every NRC licensee using the Rb-82/ Sr-82 generator would be in non-compliance with the regulations and issued repeated violations for which there would be no acceptable corrective actions.

Discussion: The EGM provides three criteria that, if met, will permit NRC to use Enforcement Discretion and not issue violations for failure to comply with requirements for Rb-82 generator systems, in accordance with 10 CFR 35.60 or 10 CFR 35.63.

The criteria are described in detail in the EGM. In general they are: (1) licensees 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, when the licensee must perform the tests, and the records that must be kept, (2) all authorized users (AUs) for medical uses under 10 CFR Part 35.200 who are using Rb-82 chloride, as well as the radiation safety officer for that licensee must have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and (3) permit the licensee to use the activity measured by the detector on the infusion cart to be used as the activity of the administration even though it is obtained slightly after the actual administration.

The EGM clarifies that 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. It also outlines what the AU and Radiation Safety Officer training has to include.

If you have any questions regarding this correspondence, please contact me or the individual named below:

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