

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

August 23, 2013

NRC REGULATORY ISSUE SUMMARY 2013-12
NOTICE OF 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

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

The intent of this regulatory issue summary (RIS) is to inform the addressees that on April 18, 2013, NRC issued 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. No specific action or written response is required. The NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees as appropriate.

BACKGROUND

The NRC, on October 1, 2007, amended its regulations (*Federal Register* (72 FR 55864)) implementing portions of the Energy Policy Act of 2005 that gave NRC regulatory authority over naturally occurring and accelerator produced radioactive materials (NARM), such as Strontium-82 (Sr-82). Through this authority, the NRC exercises jurisdiction over Rb-82/Sr-82 medical use generators.

ML13157A339

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 Strontium-85 (Sr-85) levels in excess of the concentration 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 concentration determination process. As discussed in the EGM (available at <http://pbadupws.nrc.gov/docs/ML1310/ML13101A318.pdf>), 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.

SUMMARY OF ISSUE

Without development of the EGM, every NRC licensee using the Rb-82/Sr-82 generator would be in non-compliance with the regulations in 10 CFR 35.60 and 35.63 and would be cited for repeated violations for which there would be no acceptable corrective actions. The EGM provides three criteria that, if met, will permit NRC to use Enforcement Discretion and not cite violations for failure to comply with the requirements for Rb-82 generator systems in 10 CFR 35.60 and 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, must perform the test at certain times, and must keep records documenting the performance and results of these tests; (2) all authorized users (AUs) for medical uses under 10 CFR 35.200 who are using Rb-82 chloride, as well as the radiation safety officer (RSO) for that licensee, must have successfully completed training specific to the manufacturer and model of generator and infusion cart being used; and (3) the licensee must record the activity of each dosage administered as provided by the detector on the infusion cart.

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 the training that the AU and RSO need.

FEDERAL REGISTER NOTIFICATION

The NRC did not publish a notice of opportunity for public comment on this RIS in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

The NRC has determined that this action is not subject to the Congressional Review Act (5 U.S.C. §§ 801-886) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.)

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA Pamela Henderson for/

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Enclosures:

1. EGM-3-003
2. List of Recently Issued FSME
Generic Communications

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ML13157A339 *by e-mail

| OFC | FSME/RMSB | FSME/RMSB | FSME/RMSB | OGC* | FSME/MSSA | FSME/MSSA |
|------|-----------|-----------|-----------|---------|------------|------------------------------|
| NAME | DBHowe | SGabriel | CEinberg | BJones | PHenderson | PHenderson for BMcDermott |
| DATE | 6/10/13 | 7/05/13 | 7/05/13 | 8/07/13 | 8/23/13 | 8/23/13 |

OFFICIAL RECORD COPY

| List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications | | | |
|--|------------|--|---|
| Date | GC No. | Subject | Addressees |
| 08/12/2013 | 2013-16 | Importance of Verification of Treatment Parameters for High Dose-Rate Remote Afterloader Administrations | All U.S. Nuclear Regulatory Commission (NRC) high dose-rate remote afterloader licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers. |
| 07/12/2013 | IN-2013-13 | Deficiencies with Effluent Radiation Monitoring System Instrumentation | All holders of operating licenses or a construction permit for a nuclear power reactor or a non-power reactor under Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; all holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" all holders of a materials license, certificate, approval, or registration, including those holders of and applicants for a specific source material license, under 10 CFR Part 40, "Domestic Licensing of Source Material;" all holders of and applicants for a uranium recovery operating license or construction permit under 10 CFR Part 40 which includes conventional mills, heap leach facilities, and in situ recovery facilities; all holders of and applicants for a fuel cycle facility license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;" all holders of and applicants for an independent spent fuel storage installation license under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." |

| List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications | | | |
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| Date | GC No. | Subject | Addressees |
| 06/03/2013 | RIS-2013-09 | Compressed Flammable Gas Cylinders And Associated Hazards | All holders of an operating license or construction permit for a nuclear facility under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage in the spent fuel pool. All holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." |
| 05/02/2013 | RIS-2013-08 | Pending Expiration of the NRC Type B Transportation Package Certificate for Sentinel™ Model 660 Series Radiographic Projectors on June 30, 2013 | All holders of radiography licenses for SENTINEL™ Model 660 Series radiographic projectors; all Radiation Control Program Directors and State Liaison Officers. |
| 03/25/2013 | IN-2013-06 | Corrosion In Fire Protection Piping due to Air and Water Interaction | All holders of an operating license or construction permit for a non-power reactor (research reactor, test reactor, or critical assembly) under 10 CFR Part 50, including those that have permanently ceased operations and have spent fuel in storage at their facility. All holders of and applicants for a specific source material license under 10 CFR Part 40, "Domestic Licensing of Source Material." |

| List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications | | | |
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| Date | GC No. | Subject | Addressees |
| 03/19/2013 | IN-2013-02 | Issues Potentially Affecting Nuclear Facility Fire Safety | All holders of an operating license or construction permit for a nuclear power reactor under Title 10 of the <i>Code of Federal Regulations</i> Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage in the spent fuel pool; all holders of an operating license or construction permit for a non-power reactor (research reactor, test reactor, or critical assembly) under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage at their facility; all holders of and applicants for a power reactor early site permit, combined license, standard design certification, standard design approval, or manufacturing license under 10 CFR Part 52, |

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|---|--------|---------|---|
| Date | GC No. | Subject | Addressees |
| | | | <p>“Licenses, Certifications, and Approvals for Nuclear Power Plants;” all holders of or applicants for a fuel cycle facility license under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”; all holders of or applicants for a special nuclear material license authorizing the possession, use, or transport of formula quantities of strategic special nuclear material under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material;” all holders of or applicants for an independent spent fuel storage installation license or a certificate of compliance under 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;” all holders of or applicants for a gaseous diffusion plant certificate of compliance or an approved compliance plan under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants;” all holders of and applicants for a specific source material license under 10 CFR Part 40, “Domestic Licensing of Source Material”; all State Radiation Control Program Directors and State Liaison Officers.</p> |
| <p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p> | | | |