



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

June 22, 2012

General Licensee
EA-12-126

Docket No. 99990001

Jamie Mack
Program Manager
Office of Healthy Environments
Delaware Division of Public Health
417 Federal Street
Dover, DE 19901

SUBJECT: EXERCISE OF ENFORCEMENT DISCRETION, OFFICE OF HEALTHY ENVIRONMENTS, DELAWARE DIVISION OF PUBLIC HEALTH

Dear Mr. Mack:

We are sending you this letter to document our discussions regarding your possession of X-Ray Fluorescence (XRF) devices containing byproduct material in the form of Cobalt-57 (Co-57) and to provide our conclusions regarding your compliance with NRC regulations for the devices.

During a telephone conversation on July 19, 2011, between you and Robin Elliott of this office, we learned that the Office of Healthy Environments of the Delaware Division of Public Health (the licensee) possessed three XRF devices containing 12 millicuries of Co-57 each and that the licensee had registered the devices with the State of Delaware. During a subsequent telephone conversation between you and Robin Elliott on April 17, 2012, you were informed that the regulation of Co-57 was transferred to the NRC from the State of Delaware. This change occurred with the enactment of the Energy Policy Act of 2005 (Act), and the NRC regulations resulting from the Act, which became effective on August 7, 2009. You indicated that the Office of Healthy Environments was unaware that NRC had jurisdiction and that an NRC license was required for the devices. You also stated that the devices would be stored and not used pending completion of appropriate corrective actions.

Also, during the telephone conversation of April 17, 2012, between you and Ms. Elliott, the NRC identified that the XRF devices possessed by the Office of Healthy Environments could be configured (with the appropriate labeling and documentation) as a generally-licensed (GL) device. A GL device usually consists of radioactive material contained in a sealed source within a shielded device that is designed with inherent radiation safety features so that it can be used by persons with no radiation safety experience. Consequently, a specific license under which the NRC must evaluate the adequacy of the radiation training or experience of each user is not necessary. The NRC evaluates the adequacy of GL products, ensuring that distributors meet the specific requirements in 10 CFR Part 31. Mr. Steven Courtemanche, of our staff, spoke with a representative of the device manufacturer, Radiation Monitoring Devices (RMD), and verified that RMD could prepare the appropriate documentation and provide you with the proper labels for the device to be configured to meet the NRC GL requirements. Through communication between you and Ms. Elliott on May 11, 2012, you confirmed that RMD and the Office of Healthy Environments had completed these actions.

Based on the above information, the NRC has determined that a violation of NRC requirements occurred. The violation involved the possession of byproduct material without a specific NRC license issued in accordance with the regulations in 10 CFR Part 30. Specifically, from August 7, 2009, to April 17, 2012, the Office of Healthy Environments possessed three XRF devices containing byproduct material (a sealed source containing 12 millicuries of Co-57 each). Although the devices can be configured to meet NRC GL requirements, for the period of the violation they were not, and a specific NRC license was required.

This violation would normally be categorized at Severity Level IV; however, in accordance with NRC Enforcement Guidance Memorandum (EGM) 09-004, dated May 13, 2009, the NRC will exercise discretion and not issue a violation. The NRC's decision is based on the criteria listed in EGM 09-004. Specifically, 1) this was the first occurrence the licensee was involved in after August 7, 2009, the effective date of the requirement; 2) the failure did not result in an actual safety, health or security consequence; 3) the failure was not willful; 4) the licensee, once aware of the requirements, took appropriate action; and 5) the licensee kept the device in secure storage from April 2012 until procedures were completed to reconfigure it as a generally-licensed device.

On June 6, 2012, Ms. Elliott informed you of this conclusion by telephone and that a letter documenting the conclusion would be issued. No further action or response is necessary on your part. In the future, should the Office of Healthy Environments want authorization to possess byproduct material that is not authorized by the general license provisions in 10 CFR Part 30, the Office of Healthy Environments must submit a license application to the NRC, and receive authorization prior to receiving byproduct material.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible through the NRC website at: <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it could be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind. & Academic Users**; then **Regulations, Guidance and Communications**. The current enforcement policy is included in the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement Documents**; then **Enforcement Policy (Under "Related Information")**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Robin Elliott at 610-337-5076, if you have any questions regarding this matter.

J. Mack

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Please note that the office of the Region I USNRC Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Thank you for your cooperation.

Sincerely,

/RA/

Raymond K. Lorson, Director
Division of Nuclear Materials Safety

J. Mack

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Sincerely,

/RA/

Raymond K. Lorson, Director
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