



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 16, 2012

Docket No. 03020106
EA-12-072

License No. 06-21254-01

John Dellisanti
General Manager
Carestream Molecular Imaging
4 Research Drive
Woodbridge, CT 06252

SUBJECT: NRC INSPECTION REPORT NO. 03020106/2012001, CARESTREAM MOLECULAR IMAGING, WOODBRIDGE, CONNECTICUT SITE AND THE PREVIOUS FACILITY, NEW HAVEN, CONNECTICUT, AND NOTICE OF VIOLATION

Dear Mr. Dellisanti:

On February 23 and 24, 2010, Farrah Gaskins of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. On February 15 and 16, and March 5, 2012, Dennis Lawyer of this office, conducted a safety inspection at the above address, and your previous facility at 4 Science Park, New Haven, Connecticut of activities authorized by the above listed NRC license, and as authorized under a general license you held for the possession of an LKB-Wallac RackBeta Model 1217 liquid scintillation counter containing 10 microcuries of radium-226 in the form of a sealed source. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated April 5, 2010, February 28, 2012, March 4, 9, and 10, 2012, and the telephone conversation on March 28, 2012, between Dr. Douglas Vizard, Radiation Safety Officer of your organization, and this office were also examined as part of the inspection. The findings of the inspection were discussed with Dr. Vizard of your organization at the conclusion of the inspection on March 28, 2012.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to properly dispose of specifically licensed radioactive material in the form of tritium waste; 2) the failure to deface radioactive material labels prior to releasing the material to an unrestricted area; and 3) the failure to properly dispose of a generally licensed radium-226 sealed source.

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from 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 can 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 Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on 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 Dennis Lawyer at (610) 337-5366 if you have any questions regarding this matter.

Sincerely,

Original signed by Judith A. Joustra

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Douglas Vizard, Ph.D., Radiation Safety Officer
State of Connecticut

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Judith A. Joustra, Chief
 Commercial and R&D Branch
 Division of Nuclear Materials Safety

Enclosure:
 Notice of Violation

cc:
 Douglas Vizard, Ph.D., Radiation Safety Officer
 State of Connecticut

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 D. J. Holody, RI

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OFFICE	DNMS/RI	N	DNMS/RI	ORA/R1	DNMS/RI
NAME	FGaskins/fcg		DLawyer/drl	MMcLaughlin/mmm	JJoustra/jaj
DATE	04/11/12		04/16/12	04/11/12	04/16/12

NOTICE OF VIOLATION

Carestream Molecular Imaging
Woodbridge, CT

Docket No. 03020106
License No. 06-21254-01
EA-12-072

During an NRC inspection conducted on February 23 and 24, 2010, February 15, 16, and March 5, 2012, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by specified procedures.

Contrary to the above, during October 2009, the licensee disposed of approximately 34 uCi of tritium waste by releasing this material to municipal waste, a disposal method not authorized by 10 CFR 20.2001.

This is a Severity Level IV violation (Section 6.7).

- B. 10 CFR 20.1904(b) requires that, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, each licensee remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

Contrary to the above, on August 13, 2010, the licensee transferred empty uncontaminated containers labeled as containing phosphorus 32 to an unrestricted area without first removing or defacing the radioactive material label or otherwise indicating that the containers no longer contained radioactive material.

This is a Severity Level IV violation (Section 6.7).

- C. 10 CFR 31.5(c)(8)(i) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State or as otherwise approved by 10 CFR 31.5(c)(8)(iii).

Contrary to the above, during October 2009, the licensee disposed of a LKB-Wallac RackBeta Model 1217 liquid scintillation counter containing a 10 microcurie sealed source of radium-226. This disposal was made to a person who did not hold a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State or as otherwise approved by 10 CFR 31.5(c)(8)(iii) to receive the device, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was disposed and moved to Sims Metal Management which was not licensed to receive the device containing the radium-226 source.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Carestream Molecular Imaging is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 16 day of April 2012