UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 16, 2010

Kamalesh Lahiri, M.D.
Radiation Safety Officer
Cardiovascular Diagnostics
18500 West 12 Mile Road
Southfield, Michigan 48076

SUBJECT: NRC INSPECTION REPORT NO. 030-31987/10-01(DNMS) AND NOTICE OF VIOLATION – CARDIOVASCULAR DIAGNOSTICS

Dear Dr. Lahiri:

On November 10, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at your Detroit, Michigan facility, with continued NRC in-office review through November 23, 2010. The in-office review was related to a discussion of license termination activities. A telephone exit meeting between yourself, Andrew Bramnik of my staff, and I was conducted on November 23, 2010, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations involved the failure to: (1) secure from unauthorized removal or access one cesium-137 reference source located in the hot lab, which is a controlled area; (2) conduct semi-annual physical inventories to account for all sealed sources possessed under the NRC license; and (3) provide notification to the NRC in writing within 60 days after no principal activities under the license had been conducted for a period of 24 months. Your proposed corrective actions to address the above violations were discussed between yourself and members of the NRC staff during the site inspection and via telephone.

The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in the enclosed Inspection Report No. 030-31987/10-01(DNMS). The violations are being cited because they 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. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation

of Corrective Action," may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

As immediate corrective actions for the first violation, the NRC inspector verified that the hot lab was closed and locked before leaving your facility. As long term corrective actions, you stated that you will transfer the cesium-137 source to an entity authorized to possess it as part of license termination activities. In your response, please provide the expected date when these actions will be complete.

In response to the second violation, you stated that you conduct semi-annual inventories of sealed sources possessed under your NRC license. In a November 23, e-mail, the NRC asked you to provide copies of your two most recent leak tests for your cesium-137 source. In response to the second violation, please provide copies of the two most recent semi-annual physical inventories conducted at your facility, as well as the information requested in the attached Notice. As long-term corrective actions for this violation, you stated that you will transfer your cesium source to an entity authorized to possess it as part of license termination activities.

The root cause of the third violation was a lack of awareness of the requirements in Title 10 of the Code of Federal Regulations (CFR) Part 30.36(d) to provide notification to the NRC in writing within 60 days after no principal activities under the license had been conducted for a period of 24 months. In a November 23, e-mail, the NRC provided a list of information for you to submit to the NRC Region III office to terminate your license. In your response, please provide information regarding any of these actions that have been completed or will be completed, and the expected date when these actions will be complete.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-31987
License No. 21-26259-01

Enclosure:
1. Notice of Violation
2. Inspection Report No. 030-31987/10-01(DNMS)

cc w/ encl: State of Michigan

NOTICE OF VIOLATION

Cardiovascular Diagnostics
Southfield, Michigan

Docket No. 030-31987
License No. 21-26259-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 10, 2010, with continued NRC in-office review through November 23, 2010, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the Code of Federal Regulations (CFR) Part 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on November 10, 2010, the licensee did not secure from unauthorized removal or limit access to one cesium-137 reference source located in the hot lab, which is a controlled area. Specifically, the hot lab door was unlocked, open, and accessible without supervision.

This is a Severity Level IV violation (Section 6.7.d.6).

B. Title 10 CFR 35.67(g) states that a licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

Contrary to the above, the licensee failed to conduct a semi-annual physical inventory to account for all sources and/or devices received and possessed under the license between July 22, 2008, and November 9, 2010, an interval that exceeds 6 months.

This is a Severity Level IV violation (Section 6.3.d.3).

C. Title 10 CFR 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences:

1. The license has expired,
2. The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements,
3. No principal activities under the license have been conducted for a period of 24 months, or
4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

Contrary to the above, as of November 23, 2010, no principal activities had been conducted for a period of 24 months, and the licensee failed to notify the NRC in writing within 60 days of this occurrence. Specifically, the licensee had not conducted principal activities since July 22, 2008, and the licensee had not notified the NRC prior to November 23, 2010.

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

Pursuant to the provisions of 10 CFR 2.201, Cardiovascular Diagnostics is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, 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 or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, 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, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 16th day of December 2010.

Enclosure

INSPECTION RECORD

Region III **Inspection Report No.** 030-31987/10-01(DNMS)
License No. 21-26259-01 **Docket No.** 030-31987

Licensee (Name and Address):
Cardiovascular Diagnostics
18500 West 12 Mile Road
Southfield, Michigan 48076

Licensee Contact: Kamalesh Lahiri, M.D. – RSO **Telephone No.** 248-557-5650

Priority: 5 **Program Code**: 2201

Date of Last Inspection: 11/30/2005 **Date of This Inspection**: 11/10/2010 with continued in-office review through 11/23/10 to discuss license termination activities

Type of Inspection: () Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: 11/2015 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector _____ Date 12/16/10

Andrew M. Bramnik, Health Physicist, Materials Inspection Branch

Approved _____ Date 12/16/10

Tamara E. Bloomer, Chief, Materials Inspection Branch

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No.	Date	Subject
3	2/5/2001	License Renewed in Entirety

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during prior inspections on November 30, 2005 and November 17, 1999.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee operated a private cardiac clinic with a main office in Southfield, Michigan, and was authorized to possess and use any byproduct material identified in Title 10 of the Code of Federal Regulations (10 CFR) Part 35.100 and 35.200. At the time of the inspection, the licensee had not received or administered any radioactive material since July 22, 2008.

The radiation safety officer (RSO) was the clinic owner and one of two authorized users listed on NRC License No. 21-31987-01. As of the inspection, the licensee did not employ a nuclear medicine technologist and did not retain a consulting physicist on contract. The licensee employed between one and three additional staff as office and physicians assistants.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: Sections 03.01 through 03.07

This inspection included observations of the licensee's facility, review of available records, interviews with the RSO, and independent measurements.

As mentioned in Section 1 above, the licensee had not received or administered radioactive materials since July 22, 2008. A tour of the licensee's facility revealed that the imaging suite (containing the hot lab) and the patient room suite were accessed through different doors from a common outer lobby. The inspector noted that small construction and repair equipment was stored in the imaging suite. The RSO stated that he had experienced a flood in this suite, which contributed to the area being unsuitable for use.

During the inspection, the door to the imaging suite was unlocked and not under surveillance by the licensee. Within the imaging suite, the door to the hot lab was unlocked and open. The hot lab contained one cesium-137 reference source, two cobalt-57 flood sources, and one cesium-137 check source. The cobalt-57 sources had decayed to radiation levels indistinguishable from background. On the floor outside the hot lab, the inspector also identified a transportation package marked with a Radioactive WHITE-I label and shipping information for a GE radiopharmacy located in Livonia, Michigan. The package contained one unused dose of technicium-99m, dated July 22, 2008. The cesium reference source was the only source of radioactive materials in either the hot lab or the transportation package that was determined to be greater than 10 times the levels in Appendix C to 10 CFR 20. This item is discussed in greater detail in Section 4 below.

The inspector reviewed available records from when the licensee was conducting principal activities under their NRC license. Logs describing the receipt of packages containing radioactive materials indicated that the last package was received on July 22, 2008, and that packages had been appropriately surveyed upon receipt. The records also indicated that the licensee had only used technetium-99m and thallium-201

doses. The inspector did not identify any package wipe test results in excess of regulatory limits between September 2005 and July 2008. Daily area survey and weekly wipe survey were available for the time period between September 2005, and July 2008, and did not indicate any levels above the licensee's trigger values. The most recent program audit by a consulting physicist was conducted in June 2008 and did not identify any concerns.

The RSO stated in interviews that he performed an annual review of the material in the hot lab. The RSO also stated that an individual had performed an inspection of his facility in 2009, and indicated that there were no issues with his nuclear medicine program. The RSO stated that this individual did not provide any documentation of her visit.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Independent dose rate and count rate measurements taken did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. The inspector took surveys in the hot lab, the imaging suite, near apparent injection sites, and on imaging camera beds. No area survey readings were distinguishable from background.

Records of personal dosimetry did not indicate doses in excess of 10 CFR Part 20 limits between 2005 and 2008.

The licensee possessed one Ludlum Model No. 14C survey meter with a Ludlum Model No. 44-7 detector that was last calibrated on September 30, 2008. Because the licensee had not conducted principal activities under their NRC license since July 22, 2008, confirmatory measurements were not obtained.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on November 10, 2010, the licensee did not secure from unauthorized removal or limit access to one cesium-137 reference source located in the hot lab, which is a controlled area. Specifically, the hot lab door was unlocked, open, and accessible without supervision.

The root cause of this violation was the licensee's lack of awareness of the requirement to secure reference sources of radioactive materials. The licensee's choice to not employ either a nuclear medicine technologist or a consultant physicist was a contributing cause.

As corrective actions, the inspector verified that the licensee secured the hot lab before leaving. During a November 23, 2010 telephone conversation with the Chief, Region III Materials Inspection Branch (MIB), the RSO committed to transfer the cesium-137 source to an entity authorized to possess it as part of license termination activities.

B. Title 10 CFR 35.67(g) states that a licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall

conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

Contrary to the above, the licensee failed to conduct a semi-annual physical inventory to account for all sources and/or devices received and possessed under the license between July 22, 2008 and November 9, 2010, an interval that exceeds 6 months.

During a November 23, 2010 telephone conversation with the Chief, MIB, the RSO stated that he performed leak tests of the cesium reference source every six months. During the telephone conversation, and in a subsequent e-mail that day, the NRC requested the licensee to provide records of the two most recent leak tests performed by the licensee. The RSO stated that he performed annual inspections of the hot lab, but was not able to produce documentation of these walk-throughs during the inspection. The licensee's choice to not employ either a nuclear medicine technologist or a consultant physicist was a contributing cause.

As corrective actions, the licensee will conduct a leak test on their cesium reference source. All other sources the licensee possessed had decayed such that their radiation levels were indistinguishable from background. Therefore, the leak test documentation may suffice to account for all sources and/or devices received and possessed under the license. As long term corrective action, the licensee will transfer the cesium source to an individual authorized to possess it.

C. Title 10 CFR 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences:

a. The license has expired,
b. The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements,
c. No principal activities under the license have been conducted for a period of 24 months, or
d. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

The root cause of this violation was the licensee's lack of awareness of the requirement to notify the NRC in writing after no principal activities under the license had been conducted for 24 months. The RSO stated that he continued to pay the NRC license fee because he had hoped to sell his equipment and sources to any potential buyers. The licensee's choice to not employ either a nuclear medicine technologist or a consultant physicist was a contributing cause. Additionally, the RSO stated that an individual had informed him in 2009 that there were no issues with his program.

As corrective actions, the licensee will properly dispose of all radioactive materials or transfer them to individuals authorized to possess them, and then terminate his NRC license. The inspector provided a list of information needed to terminate the NRC license to the RSO via e-mail on November 23, 2010.

5. **PERSONNEL CONTACTED**:

*& Kamalesh Lahiri, M.D. – Owner and RSO

* Individual(s) present at November 10, 2010 preliminary on-site exit meeting
& Individual(s) present at November 23, 2010, telephone exit meeting

-END-

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-31987
License No. 21-26259-01

Enclosure:
1. Notice of Violation
2. Inspection Report No. 030-31987/10-01(DNMS)

cc w/ encl: State of Michigan

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