



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

March 17, 2008

Docket No. 03037437

License No. 29-31231-01

Joseph R. Manni
Director, Support Services
Advanced Heart, Lung & Vascular Care
200 Trenton Road
Browns Mills, NJ 08015

SUBJECT: INSPECTION 03037437/2008001, ADVANCED HEART, LUNG & VASCULAR CARE, 163 ROUTE 130 NORTH, BORDENTOWN, NEW JERSEY AND NOTICE OF VIOLATION

Dear Mr. Manni:

On February 27, 2008, Todd Jackson of this office conducted a safety inspection at the Mastori's Professional Plaza, Building #2, 163 Route 130 North, Bordentown, New Jersey, of activities authorized by the above listed NRC license. 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 inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Dr. Harry Lessig, Ms. Rita Lauderman, and Ms. Rebecca Wurmbrandt of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at www.nrc.gov ; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov ; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement**; then **Enforcement Policy**. 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 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

J. Manni
Advanced Heart, Lung & Vascular Care

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Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Harry J. Lessig, M.D., Radiation Safety Officer
State of New Jersey

J. Manni
Advanced Heart, Lung & Vascular Care

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Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

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Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Harry J. Lessig, M.D., Radiation Safety Officer
State of New Jersey

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DOCUMENT NAME: C:\FileNet\ML080790482.wpd
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NAME	TJackson		JDwyer					
DATE	3/17/2008		3/17/2008					

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NOTICE OF VIOLATION

Advanced Heart, Lung & Vascular Care
Browns Mills, NJ

Docket No. 03037437
License No. 29-31231-01

During an NRC inspection conducted on February 27, 2008, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.63(d) requires that, unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, dosages were used on several occasions that did not fall within the prescribed dosage range and the dosages were not otherwise directed by the authorized user. Specifically, dosages used were outside the prescribed dosage range of 20-30 millicuries for the ungated stress procedure on five occasions between June 21, 2007 and January 16, 2008.

This is a Severity Level IV violation (Supplement VI).

- B. Condition 15 of License No. 29-31231-01 requires, in part, that the licensee conduct its program in accordance with the statements contained in the application dated March 27, 2007. Item 8 of the referenced application states that the facility will follow the Model Training Program as listed in Appendix A of Regulatory Guide 10.8, Rev. 2, which states, in part:

"Personnel will be instructed: 1. Before assuming duties with, or in the vicinity of, radioactive materials.", and

"Instruction for individuals in attendance will include the following subjects: 4. Appropriate radiation safety procedures."

Contrary to the above, personnel in the licensee's office did not receive instruction before assuming duties with, or in the vicinity of, radioactive materials at the licensee's location of use. Specifically, the licensee's initial training was conducted on August 16, 2007, which was after the first patient procedure was performed on June 21, 2007. Inadequate personnel training in the appropriate procedures also contributed to the improper initial set up and operation, through February 27, 2008, of the licensee's well counter.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Advanced Heart, Lung & Vascular Care 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.

Dated This 17 day of March 2008