



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

May 1, 2008

Docket No. 03009926

License No. 29-02957-13

Maryann Master  
Senior Vice President  
University of Medicine and Dentistry of New Jersey  
Newark Campus  
ADMC Building-3, Room 304  
30 Bergen Street  
P.O. Box 1709  
Newark, NJ 07101-1709

**SUBJECT: INSPECTION 03009926/2008001, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, NEWARK CAMPUS, NEWARK, NEW JERSEY AND NOTICE OF VIOLATION**

Dear Ms. Master:

On April 8-10, 2008, Shirley Xu of this office conducted a safety inspection at the above address 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 selective examination of representative records. The findings of the inspection were discussed with Mr. Brendan McCluskey 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.

In addition to the violations, within the scope of this inspection, two Non-Cited Violations (NCV) of 10 CFR 20.2001 and 10 CFR 35.40 were identified. Failure to follow 10 CFR 20.2001(a) to dispose 250 microcuries of Phosphorus-32 (P-32), and failure to complete Written Directives (RD), as required, for manual brachytherapy in 2007. These were non-repetitive, licensee-identified and corrected violations and are being treated as NCV in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

M. Master  
University of Medicine and Dentistry of New Jersey

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Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://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](http://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).

Please contact Shirley Xu at 610-337-5006 if you have any questions regarding this matter.

Sincerely,

***Original signed by Pamela J. Henderson***

Pamela J. Henderson, Chief  
Medical Branch  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

cc:  
Venkata K. Lanka, Radiation Safety Officer  
State of New Jersey

M. Master  
University of Medicine and Dentistry of New Jersey

2

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Pamela J. Henderson, Chief  
Medical Branch  
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Enclosure:  
Notice of Violation

cc:  
Venkata K. Lanka, Radiation Safety Officer  
State of New Jersey

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## NOTICE OF VIOLATION

University of Medicine and Dentistry of New Jersey  
Newark, NJ

Docket No. 03009926  
License No. 29-02957-13

During an NRC inspection conducted on April 8-10, 2008, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on April 9, 2007, the licensee did not secure from unauthorized removal or limit access to vials containing 940 microcuries ( $\mu\text{Ci}$ ) of Iron-55, 330  $\mu\text{Ci}$  of Carbon-14 and 26 millicuries of Tritium contained in an unlocked box inside an unlocked refrigerator located in an unattended laboratory.

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

- B. 10 CFR 35.633(b)(5) requires, in part, that full calibration measurement must include determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, as of April 10, 2008, the licensee did not determine timer accuracy and linearity over the range of use for the high dose rate remote afterloading (HDR) unit. Specifically, the licensee treated patients up to a treatment shot duration of approximately 250 seconds, however timer accuracy and linearity measurements were performed for a maximum duration of 150 seconds.

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

Pursuant to the provisions of 10 CFR 2.201, University of Medicine and Dentistry of New Jersey 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 1 day of May 2008