

November 30, 2006

EA-06-228

Mr. Anthony Costabile
Vice President for Professional Service
St. Peter's University Hospital
254 Easton Avenue
P.O. Box 591
New Brunswick, NJ 08903-0591

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 03002502/2006001)

Dear Mr. Costabile:

This letter refers to the NRC inspection conducted at your facility on August 2, 2006, as well as reviews of additional information you provided to the NRC through September 18, 2006. During the inspection, the NRC reviewed the circumstances associated with apparent violations of NRC requirements including the failure to maintain control and constant surveillance of licensed material contained in a high dose rate afterloader (HDR) unit. The results of the inspection were discussed with you and members of your staff during an exit meeting following the inspection, and were described in a letter and inspection report sent to you on October 6, 2006.

On October 4, 2006, Pamela Henderson of my staff informed you that the NRC was considering escalated enforcement action for one of the apparent violations and that the NRC did not need any additional information to make an enforcement decision. Nonetheless, Ms. Henderson provided you an opportunity to attend a predecisional enforcement conference (PEC) or to provide a written response, prior to the NRC determining appropriate enforcement action. During that conversation, you asked for additional time to consider your response and on October 10, 2006, you indicated that you wished to attend a PEC.

On November 8, 2006, the PEC was conducted with you and your staff to discuss the apparent violations, their causes, and your corrective actions. At this conference, you:

- (1) acknowledged the facts surrounding the event as presented in the inspection report;
- (2) stated that the staff at St. Peter's University Hospital takes the security of licensed material very seriously; and
- (3) described your corrective actions to prevent recurrence of the violation.

A summary of this conference is enclosed.

Based on the information developed during the inspection, and our review of the information you provided through September 18, 2006 and during the PEC, the NRC has determined that four violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The most significant violation involved the failure to secure licensed material from unauthorized removal or access, and/or maintain constant surveillance of licensed material that was stored in a controlled or unrestricted area. Specifically, on August 2, 2006, an HDR unit containing Iridium-192 was left unsecured and unattended in that the door to the room housing the HDR was open and no staff member was in the immediate vicinity to maintain constant surveillance, contrary to 10 CFR 20.1801 and 10 CFR 20.1802.

In this case, the failure to maintain constant surveillance and control of the HDR unit did not result in removal of the source from its shielded position. Furthermore, there is no evidence that unauthorized persons came into direct contact with the device during the time that it was unsecured and unattended. Nonetheless, this violation is of concern to the NRC because the failure to control radioactive material could result in the loss or theft of the material; and significant unintended radiation doses to members of the public could occur if the source was removed from its shielded position. Therefore, this violation is categorized at Severity Level III in accordance with the NRC Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,250 is considered for a Severity Level III violation involving the loss of control of radioactive material with this level of radioactivity. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions, which you described during the PEC held on November 8, 2006, included, but were not limited to: (1) immediately storing the keys to the chain securing the HDR to the floor and the keys to the unit and the console in the physics office; (2) installing a lock box with a combination code to secure the keys; (3) placing the HDR unit in a lockable stainless steel cabinet; (4) revising the HDR security protocol; (5) providing training to the staff to reinforce the HDR security requirements; and (6) initiating random HDR security inspections (twice daily).

Therefore, to encourage prompt and comprehensive identification and correction of violations, and in recognition of the absence of previous escalated enforcement action at your facility within the last two years and two inspections, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The three additional violations identified as a result of the inspection are included in the enclosed Notice and are categorized at Severity Level IV in accordance with Supplement VI.D of the Enforcement Policy. Although none of these violations warrant escalated enforcement action, these violations in conjunction with the Severity Level III violation discussed above demonstrate the need for increased management attention to your radiation safety program.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, in your letter dated September 18, 2006, in the inspection report issued on October 6, 2006, and in the additional information you provided at the November 8, 2006, PEC. Therefore, you are not required to respond to this letter unless the description herein, as well as in the inspection report, does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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. The NRC also includes significant enforcement actions on its web site at <http://www.nrc.gov>; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ Original Signed By Marc L. Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 030-02502
License No. 29-07566-01

Enclosures: 1. Notice of Violation
2. Enforcement Conference Summary

cc: State of New Jersey

DISTRIBUTION w/encl:

ADAMS (PARS)
 SECY
 CA
 OEMAIL
 OEWEB
 L Reyes, EDO
 M Virgilio, DEDMRT
 C. Carpenter, OE
 S. Merchant, OE
 L. Sreenivas, OE
 B Jones, OGC (Bradley)
 L Chandler, OGC
 C Miller, FSMEP
 B. Sosa, OEDO
 Enforcement Coordinators
 RII, RIII, RIV
 L. Lopez, OE
 O. Samuel, OE
 M Elwood, OGC
 S Gagner, OPA
 H Bell, OIG
 J. Schlueter, FSME
 D. Rathbun, FSME
 G Caputo, OI
 L Tremper, OCFO
 D Screnci, PAO-RI
 N Sheehan, PAO-RI
 G Pangburn, FSME
 P. Henderson, RI
 B. Holian, RI
 K Farrar, RI
 D Holody, RI
 J Wray, RI
 R Summers, RI
 C O'Daniell, RI
 S. Villar, RI
 Region I OE Files (with concurrences)

SUNSI Review Complete: jdk (Reviewer's Initials)

DOCUMENT NAME: C:\FileNet\ML063340582.wpd

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/ORA	RI/ORA
NAME	JWray*	PHenderson *	GPangburn*	KFarrar	DHolody
DATE	11/08/06	11/08/06	11/15/06	11/15/06	11/16/06
OFFICE	HQ/NMSS	HQ/OE	RI/RA		
NAME	GMorell	MJohnson	SCollins/MLD for		
DATE	11/21/06	11/27/06	11/30/06		

OFFICIAL RECORD COPY

*concurrence on previous page ** via e-mail from SMerchant to JWray

ENCLOSURE

NOTICE OF VIOLATION

St. Peter's University Hospital
New Brunswick, New Jersey

Docket No. 030-02502
License No. 29-07566-01
EA-06-228

Based on an NRC inspection conducted at the St. Peter's University Hospital in New Brunswick, New Jersey, on August 2, 2006, as well as reviews in the Region I office until September 18, 2006, the date on which an exit meeting was held, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is 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 August 2, 2006, the licensee did not secure from unauthorized removal or limit access to and maintain constant surveillance over licensed material. Specifically, the door to the treatment room containing a High Dose Rate Remote Afterloader (HDR) containing licensed material was open, there was no staff member in the immediate area of the treatment room to maintain surveillance, the key to the chain securing the HDR unit to the floor of the treatment room was stored in an unlocked cabinet directly above the HDR unit, and, therefore, the HDR unit was not secure from unauthorized removal.

This is a Severity Level III violation (Supplement IV)

- B. 10 CFR 35.610 (a)(1) requires, in part, that the HDR console, the HDR console keys, and the treatment room be secured when not in use or unattended.

Contrary to the above, on August 2, 2006, the licensee failed to secure the HDR console, the HDR console keys, and the treatment room. Specifically, the keys to the HDR console were stored in an unlocked cabinet directly above the HDR unit and the door to the treatment room was not locked or otherwise secured.

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

- C. 10 CFR 35.92(b) requires that the licensee retain a record of each disposal permitted under 10 CFR 35.92(a) as decay-in-storage. 10 CFR 35.92(a) specifies that, under certain conditions, a licensee may dispose of byproduct material with a physical half-life of less than 120 days by holding it for decay until its radioactivity cannot be distinguished from background radiation.

Contrary to the above, as of August 2, 2006, the licensee did not maintain records of all disposals of licensed material contrary to 10 CFR 35.92. Specifically, the licensee held

unused Iodine 131 capsules for decay-in-storage, and as of August 2, 2006, the licensee did not maintain records of the disposal of this licensed material.

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

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

Contrary to the above, the license did not determine timer linearity over the typical range of use. Specifically, as of August 2, 2006, the licensee's typical treatment range of use was 720 seconds, and timer linearity checks were only performed over 60 seconds.

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

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, in your letter dated September 18, 2006, in the inspection report issued on October 6, 2006, and in the additional information you provided at the November 8, 2006, predecisional enforcement conference. Therefore, no response to this Notice is required. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-06-228" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 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).

If you contest the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555.

Because any response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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).

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

Dated this 30th day of November 2006