

April 30, 2007

EA-06-309

Mr. Daniel Markham
Vice President
Englewood Hospital and Medical Center
350 Engle Street
Englewood, NJ 07631

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$3250 (NRC Inspection Report No. 03002513/2005001 and Investigation Report
No. 1-2005-017)

Dear Mr. Markham:

This refers to the NRC inspection conducted on April 13 and September 1, 2005, as well as a subsequent investigation by the NRC Office of Investigations (OI) completed on April 21, 2006. During the inspection and investigation, six apparent violations of NRC requirements were identified. The apparent violations of NRC requirements were documented in an inspection report and factual summary of the OI investigation, which we sent to you in a letter dated January 25, 2007. The inspection findings were previously discussed with you and/or members of your staff during exit meetings on April 13, 2005, September 1, 2005, May 9, 2006, and January 16, 2007.

On February 27, 2007, a predecisional enforcement conference (PEC) was conducted in the Region I office with you and members of your staff to discuss the apparent violations, their significance, root causes and your corrective actions. Based on the results of the NRC inspection and investigation, as well as the information provided at the PEC, the NRC has determined that six violations of NRC requirements occurred. The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The three most significant violations involved: (1) submittal of inaccurate information to the NRC in support of a request to amend your license to add an individual as an Authorized Medical Physicist (AMP); (2) failure to adequately control or maintain constant surveillance of your high dose-rate remote afterloader (HDR) unit containing licensed material; and, (3) failure to appoint a Radiation Safety Officer (RSO) for a period of approximately two months in 2005.

With respect to the first violation, an AMP provided you a preceptor statement that listed the qualifications and experience of an individual that you requested NRC to approve as an AMP. The preceptor statement was inaccurate in that it indicated that the individual met the required training and experience to be named as an AMP, including having clinical experience at your facility from December 2004 to May 2005, when in fact, the individual had not begun work at your facility until February 2005. Based on the OI investigation, the NRC concluded that the actions of the AMP were deliberate in that he knew that the preceptor statement was inaccurate at the time it was submitted to you. Since you are responsible for the acts of your employees,

contractors and their employees, your submittal of the inaccurate information to the NRC was determined to be a deliberate violation of the NRC requirements.

In assessing the significance of the violation, the NRC considered that your requests to add an individual to your NRC license, who did not meet NRC requirements, could have resulted in an inexperienced physicist conducting licensed activities. The NRC also considered that prior to your submittal of the inaccurate information, you did not take action to confirm the accuracy of the information. Although there were no actual health and safety consequences to the public that resulted from this violation, the NRC has decided, based on the deliberate nature of the violation, to classify the violation 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. Because this violation was willful, the NRC considered whether credit was warranted for both Identification and Corrective Action in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit is not warranted for identification because the violation was identified by the NRC. Credit is warranted for corrective actions because the actions were considered to be comprehensive. The actions included plans to ensure that documents related to license amendment requests are carefully reviewed by the medical center's management. We also understand that you have replaced the AMP following his voluntary separation.

To emphasize the importance of assuring that information provided to the NRC is complete and accurate in all material respects, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$3,250. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

With respect to the second violation, involving the failure to ensure that the HDR is under constant surveillance or secured from unauthorized removal, the NRC recognizes that the likelihood of illicit removal of the HDR source was low because (1) the radioactive material was locked in the HDR unit; (2) the unit "beeps" when disconnected from the AC power, making unauthorized removal more likely to be detected; and, (3) even though the unit's console keys were unsecured in the room, an individual would also need a password to remove the source. However, if the source had been subsequently removed from the unit, exposures from the unshielded source could have potentially resulted in significant exposures to radiation. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the Enforcement Policy, the third violation regarding the failure to appoint a Radiation Safety Officer for a period of approximately two months, is also classified at Severity Level III.

Because your facility has not been the subject of escalated enforcement actions within the last two years or two inspections, the NRC, in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy, considered whether credit was warranted for *Corrective Action* for the second and third violations (Violations II.A. and II.B. in the Notice). Credit for corrective action is warranted because the NRC considers your actions to be comprehensive. The corrective actions, which were provided in letters dated April 15, 2005,

September 7, 2005, May 9, 2006, and February 26, 2007, as well as during the PEC, included: (1) securing your HDR unit in a container within the treatment room, and securing the keys to the unit; (2) amending your license to name a new RSO; and, (3) committing to make timely decisions on naming replacement RSOs and maintaining better communication with the NRC on such matters.

Therefore, to emphasize the importance of comprehensive corrective actions whenever violations are identified at your facility, I have been authorized, after consultation with the Director, Office of Enforcement, to not issue a civil penalty for violations II.A and II.B. The other three violations documented in the enclosed Notice (Violations II.C, II.D, and II.E) have been classified at Severity Level IV. Corrective actions for these violations have also been described in your previous letters and found to be acceptable.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in the letter transmitting this Notice; in the aforementioned letters from EHMC; and/or during transcribed discussions at the PEC. Therefore, although you are required to provide a response to the Notices of Violation and Proposed Imposition of Civil Penalty, you are not required to respond to the provisions of 10 CFR 2.201 (which would require you to describe your corrective actions), unless the description herein 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. 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.

Alternatively, you may request alternate dispute resolution (ADR) with the NRC in an attempt to resolve the issues. If you request ADR in an attempt to resolve the issues, you will need to contact the Institute on Conflict Resolution (ICR) at 877-733-9415 within 10 days of the date of this letter. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program, which is now in effect, is mediation. Additional information is provided in the brochure (NUREG/BR-0317) that was provided to you in our January 25, 2007 letter, and can be obtained at <http://www.nrc.gov>. The ICR at Cornell University has agreed to facilitate the NRC's program as an intake neutral.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/>; select **About NRC, Organizations & Functions, Office of Enforcement, About Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ Original Signed by Marc Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 030002513
License No. 29-08519-01

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (licensee only)

cc:

Lawrence Saperstein, M.D., Radiation Safety Officer
State of New Jersey

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **About NRC, Organizations & Functions, Office of Enforcement, About Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ Original Signed by Marc Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 030002513
License No. 29-08519-01

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (licensee only)

cc:

Lawrence Saperstein, M.D., Radiation Safety Officer
State of New Jersey

DISTRIBUTION:

ADAMS (PARS)	GPangburn, FSME	DScreni/NSheehan, PAO-RI
SECY	JSchlueter, FSME	BHolian, RI
CA	DRathbun, FSME	PHenderson
OEMAIL	Enforcement Coordinators	KFarrar, RI
OEWEB	RII, RIII, RIV	DHolody, RI
LReyes, EDO	LLopez, OE	ADeFrancisco, RI
MVirgilio, DEDMRT	OSamuel, OE	RSummers, RI
CCarpenter, OE	GVenegiano, OGC	CO'Daniell, RI
SMerchant, OE	EHayden, OPA	SVillar, RI
LSreenivas, OE	HBell, OIG	R1DNMS_Mail
BJones, OGC	GCaputo, OI	Region I OE Files (with concurrences)
LChandler, OGC	JLamb, OEDO	
CMiller, FSME		

SUNSI Review Complete: pjh (Reviewer's Initials)

DOCUMENT NAME: Englwd Lic.pkg false preceptor SLIII+CP.wpd ADAMS Document Accession No.: ML071200025

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/OR	RI/DNMS	RI/DNMS	RI/OI	RI/RC
NAME	*ADeFrancisco	*PHenderson	*BHolian	*EWilson	*KFarrar
DATE	03/23/07	03/23/07	03/26/07	03/27/07	03/28/07
OFFICE	RI/OR	FSME	OGC	OE	RI/RA
NAME	*DHolody	GMorell for CMiller	B. Klukan for B. Jones	**SMerchant	SCollins/MLD for
DATE	03/29/07	04/ 06 /07	04/03 /07	04/26/07	04/26/07

OFFICIAL RECORD COPY

*see previous concurrence page for signatures

**concurred via email

**NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY**

Englewood Hospital and Medical Center
Englewood, New Jersey

Docket No. 030002513
License No. 29-08519-01
EA-06-309

During an NRC inspection conducted on April 13 and September 1, 2005, and during an investigation by the NRC Office of Investigations (OI) completed on April 21, 2006, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. VIOLATION ASSESSED A CIVIL PENALTY

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, on April 6, 2005, Englewood Hospital and Medical Center (EHMC) submitted a license amendment request that provided information to the NRC regarding training and experience of a medical physicist (MP) which was not accurate in all material respects. The licensee submitted a preceptor statement, signed by one of its Authorized Medical Physicists (AMP), attesting that an additional MP had the required training and experience to be added to the EHMC NRC license as an AMP. This statement was inaccurate because the additional MP did not have the required training and experience as described in the preceptor statement. Specifically, the preceptor statement indicated that the additional MP received training at EHMC from December 2004 to May 2005, when, in fact, the MP did not start work at EHMC until February 2005. This statement was material because it had the capability to influence the NRC decision as to whether to approve the medical physicist as an AMP.

This is a Severity Level III violation (Supplement VII).
Civil Penalty - \$3,250

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

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 certain occasions prior to September 7, 2005, the licensee did not secure from unauthorized removal, or limit access to the high

dose-rate remote afterloader (HDR) unit containing Iridium-192, located in the linear accelerator room of the Radiation Oncology Department, which is a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, prior to September 7, 2005, the HDR unit was left unattended and unsecured from 4:00 - 5:00 P.M. each day to allow cleaning personnel access to the department.

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

- B. 10 CFR 35.24(b) requires that a licensee's management appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

License Condition 12 of license 29-08519-01 states the name of the Radiation Safety Officer.

Contrary to the above, between February 3, 2005 and April 6, 2005, the licensee's management failed to appoint a Radiation Safety Officer, who agreed, in writing, to be responsible for implementing the radiation protection program. Specifically, on February 3, 2005, the Radiation Safety Officer named in License Condition 12 was no longer employed by the licensee, and the licensee's management failed to appoint a Radiation Safety Officer for a period of approximately two months.

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

- C. 10 CFR 20.1101 requires, in part, that a licensee periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, prior to July 28, 2005, the licensee did not conduct adequate annual reviews of its radiation protection program content and implementation. Specifically, prior to that date, the annual audits of the licensee's radiation protection program were inadequate in that they did not include a review of the brachytherapy program.

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

- D. 10 CFR 35.14 requires, in part, that the licensee notify the Commission no later than 30 days from the date that the licensee permits an individual to work as an AMP under 10 CFR 35.13(b).

Contrary to the above, the licensee did not notify the Commission within 30 days from the date that they permitted two individuals to work as AMPs under 10 CFR 35.13(b). Specifically, the licensee permitted the two individuals to work as AMPs on February 6, 2005, and the Commission was not notified until April 6, 2005.

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

- E. 10 CFR 35.610 requires that the licensee secure the HDR unit, the console, the console keys, and the treatment room when not in use or unattended.

Contrary to the above, the licensee did not secure the HDR console keys when not in use or unattended. Specifically, on April 13 and September 1, 2005, the console keys were left in the console, and the console was unattended.

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

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in the letter transmitting this Notice, as well as in letters from the licensee dated April 15, 2005, September 7, 2005, May 9, 2006, and February 26, 2007. Therefore, although you are required to provide a response to this Notice of Violation and Proposed Imposition of Civil Penalty, you are not required to respond to the provisions of 10 CFR 2.201 (which would require you to describe your corrective actions), unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, clearly mark your response as a "Reply to a Notice of Violation" and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty.

Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section VI.C.2, "Civil Penalty Assessment," of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty. Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney

General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to Payment of Civil Penalty, and Answer to a Notice of Violation, should be addressed to: Cynthia Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). To the extent possible, your response should not include any personal privacy, proprietary, classified 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>. 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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 the 30th day of April 2007