



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

January 25, 2007

Docket No. 03002513
EA No. 06-309

License No. 29-08519-01

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

SUBJECT: NRC INSPECTION NO. 03002513/2005001, ENGLEWOOD HOSPITAL AND MEDICAL CENTER, ENGLEWOOD, NEW JERSEY SITE, AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2005-017

Dear Mr. Markham:

On April 13, and September 1, 2005, Shirley Xu and Thomas Thompson 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 selected examination of representative records. Additional information provided in your correspondence dated April 15, and September 7, 2005, and the telephone conversations on September 7, 2005, and May 9, 2006, between you and this office were also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this safety inspection, five apparent violations were identified, and two (1 and 2 below) are being considered for escalated enforcement. The apparent violations indicated an inadequate oversight of your brachytherapy program and included: 1) failure to adequately control or maintain constant surveillance of your high dose-rate remote afterloader (HDR) unit containing licensed material, as required by 10 CFR 20.1801/1802; 2) failure to have a Radiation Safety Officer (RSO) as required by license No. 29-08519-01, condition 12; 3) failure to fully review the radiation protection program content and implementation as required by 10 CFR 20.110(c); 4) failure to notify the Commission within 30 days from the date that you permitted two individuals to work as authorized medical physicists as required by 10 CFR 35.14(a); and 5) failure to secure the HDR console keys when not in use or unattended as required by 10 CFR 35.610(a)(1).

In addition, based on the initial NRC staff inspection findings, the NRC Office of Investigations (OI), Region I Field Office, initiated an OI Investigation. Based upon the evidence developed during this investigation, OI substantiated that Englewood Hospital and Medical Center (EHMC) provided inaccurate documentation to the NRC in a license amendment request.

As a result of this OI investigation, one apparent violation of 10 CFR 30.9(a) was identified and is being considered for escalated enforcement in accordance with the NRC Enforcement Policy. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by an applicant for a license shall be complete and accurate in all material respects. Specifically, OI determined that EHMC provided inaccurate information to the NRC in support of a request to amend their byproduct materials license to add an Authorized Medical Physicist (AMP) to the license. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**.

The results of NRC inspection activities are included in the enclosed Inspection Report No. 03002513/2005001. The results of the OI Investigation are included in the enclosed Factual Summary of OI Investigation 1-2006-017.

Before an enforcement decision is made, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC) at the Region I office. This conference will be closed and transcribed. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty of the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

Instead of a PEC, EHMC may request Alternative Dispute Resolution (ADR) with the NRC. 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 is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and EHMC) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting the parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at 607-255-1124 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please contact Ms. Pamela Henderson at (610) 337-6952 within 10 days of the date of this letter to notify the NRC of your decision to either participate in a PEC or ADR.

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>.

Your cooperation is appreciated.

Sincerely,

Original signed by Brian Holian

Brian E. Holian, Director
Division of Nuclear Materials Safety

Enclosures:

1. NRC Inspection Report No. 03002513/2005001 (**Not Publically Available**)
2. Factual Summary of OI Investigation Report No. 1-2005-017
3. Excerpts from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION"
4. NUREG/BR-0317, "Post-Investigation ADR Program"

cc:

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

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DATE					

FACTUAL SUMMARY OF OI INVESTIGATION REPORT NO. 1-2006-017

On April 18, 2005, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, initiated an investigation to determine if an unauthorized Medical Physicist (MP) was providing High Dose Rate (HDR) treatments at Englewood Hospital and Medical Center (EHMC), Englewood, New Jersey. During the investigation, additional information was obtained regarding EHMC providing inaccurate information to the NRC in a license amendment request.

Based on the evidence developed during its investigation, OI did not substantiate that an unauthorized MP was providing HDR treatments at EHMC. Interviews with seven employees and five consultants did not provide any evidence that the unauthorized MP performed HDR treatments at EHMC without proper supervision.

OI did substantiate that EHMC provided inaccurate documentation to the NRC in support of a license amendment request to add an authorized MP to its license. OI determined that a Senior Medical Physicist Consultant (an Authorized Medical Physicist (AMP) on the EHMC license who owns his own consulting business which, in part, provides qualified medical personnel to hospitals) deliberately provided inaccurate information to EHMC regarding one of his employees which caused EHMC to be in violation of NRC regulations. The amendment request, dated April 6, 2005, asked that a Junior Medical Physicist Consultant, employed by the Senior Medical Physicist Consultant, be added to the EHMC license as an AMP because she performed clinical training at EHMC from December 2004 through May 2005. This information was material to meeting the training and experience requirements of 10 CFR 35.51. OI determined that (1) the dates of that clinical training were inaccurate, (2) the Senior Medical Physicist Consultant knew that the dates were inaccurate, and (3) the time that the Junior Medical Physicist Consultant spent at EHMC prior to February 2005 did not constitute clinical training.

The evidence supporting this conclusion included: (1) a review of contractual employment records indicating that the Junior Medical Physicist Consultant began work at EHMC on February 3, 2005, and not December 2004 as indicated on the documentation submitted to the NRC, (2) the testimony of the Chief Medical Physicist for EHMC that the Senior Medical Physicist Consultant and the Junior Medical Physicist Consultant did not come to EHMC for training or employment before February 3, 2005, and (3) the admission of the Senior Medical Physicist Consultant that any time spent at EHMC prior to February 2005 by the Junior Medical Physicist Consultant was not clinical training, as indicated on the documentation submitted to the NRC.