



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

July 13, 2006

Docket No. 03007565
EA No. 06-139

License No. 07-14850-01

Dennis Klima
President/CEO
Bayhealth Medical Center
640 South State Street
Dover, DE 19901

SUBJECT: INSPECTION 03007565/2005001, BAYHEALTH MEDICAL CENTER, DOVER,
DELAWARE SITE AND NOTICE OF VIOLATION

Dear Mr. Klima:

On October 4-5, 2005, Donna Janda and Richard McKinley 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 inspectors, interviews with personnel, and a selected examination of representative records. Followup information provided through February 15, 2006 were also examined as part of the inspection. The findings of the inspection were discussed with Sheila Snyder, Director of the Cancer Center and Heather Jones, Chief Nuclear Medicine Technologist, 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. With regard to Violation A, the NRC has concluded that information regarding the reasons for the violation, the action taken to correct the violation and prevent recurrence and the date when compliance was achieved is adequately described on the docket in your letters dated October 19, 2005, and February 15, 2006. Therefore you are not required to respond to this violation unless the description therein does not accurately reflect your corrective actions or position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. With regard to Violation B., 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, industrial, and academic uses of nuclear material**; then **toolkit index page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select

D. Klima
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What We Do, Enforcement, then Enforcement Policy. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

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

Enclosure:
Notice of Violation

cc:
Sheila Snyder, Director of Cancer Center
Rachel Taylor, M.D., Radiation Safety Officer
State of Delaware

D. Klima
Bayhealth Medical Center

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NOTICE OF VIOLATION

Bayhealth Medical Center
Dover, DE

Docket No. 03007565
License No. 07-14850-01
EA No. 06-139

Based on an NRC inspection at your facility conducted on October 4-5, 2005, as well as reviews in the Region I office of additional information provided to the NRC through February 15, 2006, 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 August 12, 2005, the licensee did not secure from unauthorized removal or limit access to a vial containing 116 microcuries of cesium-137 which was located in the Nuclear Medicine Department hot lab, which is a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material.

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

- B. 10 CFR 20.2201(b)(1) requires, in part, that each licensee required to make a report under paragraph (a) of this section shall, within 30 days, after making the telephone report, make a written report setting forth certain information.

Contrary to the above, the licensee did not make a written report within 30 days after making the telephone report. Specifically, the telephone report was made on August 13, 2005, and as of October 5, 2005, no written report had been made, a period which exceeded 30 days.

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

For Violation A., the NRC has concluded that information regarding the reason for the violation, 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 your letters dated October 19, 2005, and February 15, 2006, and in the NRC letter transmitting this Notice. Therefore, no response to Violation A. 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 06-139" 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).

Notice of Violation
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For Violation B., pursuant to the provisions of 10 CFR 2.201, Bayhealth Medical Center is hereby required to submit a written statement or explanation 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, EA 06-139", 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 13th day of July 2006