



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

January 14, 2008

Docket No. 03002547

License No. 29-12253-01

Sabina Fallon
Assistant Vice President for Administration
Bayonne Medical Center
29 East Twenty-ninth Street
Bayonne, NJ 07002

SUBJECT: INSPECTION 03002547/2007001, BAYONNE MEDICAL CENTER, BAYONNE, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Ms. Fallon:

On March 9, June 14, and June 19, 2007, Sandy Gabriel 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 submitted through January 1, 2008, was also examined as part of the inspection. The findings of the inspection were discussed with you and Vito Comes of your organization at the conclusion of the on-site inspection, and by telephone with Mr. Comes on January 14, 2008.

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. The NRC has concluded that information regarding the reason for each violation, and the corrective actions taken and planned to correct each violation and prevent recurrence are already adequately addressed on the docket in our inspection record and in the letters dated September 18 and December 3, 2007; facsimiles dated April 25 and August 27, 2007; and electronic mail messages dated May 1, June 17, August 6 and 17, and December 13, 2007, and January 1, 2008.

Your corrective action for the first violation was to discontinue use of the ophthalmic applicator until the source output or activity was determined using published protocols currently accepted by nationally recognized bodies. On May 8, 2007, the applicator was shipped to the University of Wisconsin Accredited Dosimetry Calibration Laboratory (ADCL).

Your corrective actions for the second violation were to (a) retrain staff, and (b) provide documentation to the NRC that an authorized user who did not sign the written directive did intend to perform the prostate implant on the patient who was implanted on August 11, 2006. The inspector reviewed this documentation on April 27, 2007, and determined that it was unnecessary for the NRC to retain a copy.

Your corrective action for the third violation was to update your prostate implant written directive form to include the dose before implantation. A copy of the updated form was submitted as an attachment to an electronic mail message dated May 1, 2007.

Your corrective action for the fourth violation was to update high dose-rate remote afterloader (HDR) daily spot-check procedures to include verification of proper operation of source exposure indicator lights on the control console, timer accuracy, and decayed source activity in the unit's computer. A copy of the updated spot-check form was submitted as an attachment to an electronic mail message dated June 17, 2007.

Your corrective action for the fifth violation was to repeat the HDR output calibration using a dosimetry system that was calibrated within the previous two years. A record of the new HDR output calibration was submitted in a facsimile transmitted on April 25, 2007.

Your corrective action for the sixth violation was to discontinue HDR treatments until full calibration procedures were updated and a new calibration was performed that included determination of source retraction with backup battery upon power failure; timer accuracy and linearity over the typical range of use; length of the source transfer tubes and applicators; and function of the source transfer tubes, applicators, and transfer tube-applicator interfaces. A record of the new HDR full calibration was submitted in a facsimile transmitted on August 27, 2007.

Your corrective action for the seventh violation was to conduct a drill of HDR emergency procedures on June 28, 2007. Documentation of this drill was submitted as an attachment to an electronic mail message sent on August 6, 2007.

Because the NRC has concluded that the violations have already been adequately addressed, you are not required to respond to this letter 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.

Within the scope of this inspection, an additional concern was identified. Since late 2006, radiation oncology services have been provided by Bayonne Radiation Oncology Associates (BROA) and BROA's physics services have been provided by mpowered. The seven violations identified during this inspection all involved the brachytherapy program in radiation oncology, and it appeared that Bayonne Medical Center (BMC) provided no management oversight or independent auditing of this program. Prior to the conclusion of this inspection, an independent third party conducted an audit of BMC's brachytherapy program. In addition, management of BMC, BROA, and mpowered jointly submitted a plan to improve management oversight and better reflect the division of programs between BMC and BROA. The plan was described in the letters dated September 18 and December 3, 2007, and in an electronic mail message dated December 13, 2007. BROA intends to submit a new license application for use of the ophthalmic applicator and HDR, concurrent with an amendment request from BMC to remove these devices from its license. The prostate implant program will remain under BMC's license, because the operative procedures are performed in BMC's surgical suite. BROA will contract with an independent third party to perform an annual external audit of its brachytherapy program, while the primary site physicist will use a template to conduct quarterly internal audits. BMC will contract with an independent third party to perform an annual external audit of BMC's

prostate implant program. The third party will develop a template for BMC to use to conduct quarterly internal audits, under the direction of the Nuclear Medicine supervisor.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may 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).

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

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

Enclosure:
Notice of Violation

cc:
Luciano Castillo, M.D., Radiation Safety Officer
Vito Comes, Executive Director of Imaging & Vascular Services
State of New Jersey

BMC will contract with an independent third party to perform an annual external audit of BMC's prostate implant program. The third party will develop a template for BMC to use to conduct quarterly internal audits, under the direction of the Nuclear Medicine supervisor.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may 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).

Thank you for your cooperation.

Sincerely,

/RA/

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

Enclosure:
Notice of Violation

Distribution:
D. J. Holody, RI

DOCUMENT NAME: C:\FileNet\ML080150500.wpd

SUNSI Review Complete: SGabriel

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 w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	SGabriel SLG2		PHenderson pjh1				
DATE	1/14/08		1/14/08				

NOTICE OF VIOLATION

Bayonne Medical Center
Bayonne, NJ

Docket No. 03002547
License No. 29-12253-01

During an NRC inspection conducted on March 9, June 14, and June 19, 2007, seven violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.432(a) requires, in part, that before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have determined the source output or activity using published protocols currently accepted by nationally recognized bodies.

Contrary to the above, the licensee used a brachytherapy source after October 24, 2002 without determining the source output or activity using published protocols currently accepted by nationally recognized bodies. Specifically, as of March 9, 2007, the licensee performed patient treatments using a strontium-90 ophthalmic applicator that was last calibrated in 1987, and the 1987 calibration did not use published protocols currently accepted by nationally recognized bodies.

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

- B. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, on August 11, 2006, the licensee administered a therapeutic dose of radiation from byproduct material and the written directive was not dated and signed by an authorized user. Specifically, the licensee performed a manual brachytherapy prostate implant using byproduct material and the written directive had not been dated and signed by the authorized user.

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

- C. 10 CFR 35.40(b) requires, in part, that the written directive for manual brachytherapy must contain, before implantation, the patient or human research subject's name and the following information: the treatment site, radionuclide, and dose.

Contrary to the above, prior to March 9, 2007, the licensee's written directives for manual brachytherapy did not contain the information required in 10 CFR 35.40(b). Specifically, the written directives for manual brachytherapy prostate implants did not include the dose before implantation.

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

- D. 10 CFR 35.643(d) requires, in part, that spot-checks of high dose-rate remote afterloader units be performed to assure proper operation of source exposure indicator lights on the remote afterloader unit, timer accuracy, and decayed source activity in the unit's computer.

Contrary to the above, prior to March 9, 2007, the licensee performed spot-checks of a high-dose rate remote afterloader unit that did not include a check of source exposure indicator lights on the control console, timer accuracy, and decayed source activity in the unit's computer.

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

- E. 10 CFR 35.630(a) requires, in part, that (1) the dosimetry system must have been calibrated within the previous two years, or (2) the system must have been calibrated within the previous four years and, 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM).

Contrary to the above, the licensee performed full calibration measurements on a remote afterloader unit using a dosimetry system that was (1) not calibrated within the previous two years, and (2) although the system had been calibrated within the previous four years, the system had not been intercompared with another dosimetry system 18 to 30 months after that calibration with a system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. Specifically, on November 17, 2006, the licensee performed full calibration measurements using a dosimetry system that was last calibrated on April 30, 2003, and had not been intercompared with another dosimetry system that was calibrated within the past 24 months.

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

- F. 10 CFR 35.633(b) requires, in part, that full calibration measurements of high dose-rate remote afterloader units include determination of source retraction with backup battery upon power failure; timer accuracy and linearity over the typical range of use; length of the source transfer tubes and applicators; and function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

Contrary to the above, prior to March 9, 2007, the licensee's full calibration measurements of the high dose-rate remote afterloader unit did not include determination of source retraction with backup battery upon power failure; timer accuracy and linearity over the typical range of use; length of the source transfer tubes and applicators; and function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

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

- G. 10 CFR 35.610(e) requires that a licensee ensure that operators, authorized medical physicists, and authorized users participate in drills of high dose-rate remote afterloader emergency procedures initially and at least annually.

Contrary to the above, the licensee did not ensure that operators, authorized medical physicists, and authorized users participated in drills of high dose-rate remote afterloader procedures initially and at least annually. Specifically, on March 9, 2007, operators, authorized medical physicists, and authorized users had not participated in a drill of high dose-rate remote afterloader emergency procedures within the previous year.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," and send it 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).

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 14th day of January 2008