UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

August 8, 2013

EA-13-107

David McClure
Vice President of Operations
Camden-Clark Memorial Hospital Corporation
800 Garfield Avenue
Parkersburg, WV 26102

SUBJECT: CAMDEN-CLARK MEMORIAL HOSPITAL CORPORATION, NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03003390/2012001

Dear Mr. McClure:

This letter provides you the NRC enforcement decision for the four apparent violations identified during the onsite NRC inspection conducted on January 18 and 19, 2012, at the Camden Clark Memorial Hospital Corporation (CCMHC) in Parkersburg, West Virginia, as well as a subsequent in-office review that was completed on April 22, 2013. The inspection included: (1) assessment of a 15-day medical event report submitted to the NRC by CCMHC on March 5, 2012, (ML13106A274[1]); (2) review of an NRC medical consultant's report dated September 4, 2012, (non-public due to the inclusion of medical privacy information); and, (3) review of CCMHC's proposed corrective actions described in correspondence dated March 1, 2013, (ML13099A039; ML13099A058; ML13099A063; ML13099A076). Both the onsite inspection and the in-office review evaluated CCMHC's licensed activities as they relate to radiation safety and to compliance with NRC regulations. Tara Weidner, Senior Health Physicist, NRC Region I Medical Branch, discussed the apparent violations during a telephonic exit meeting with you on April 22, 2013. The apparent violations were also described in the NRC inspection report sent to you with a letter dated April 29, 2013 (ML13121A191).

In a telephone conversation on July 18, 2013, Mr. James Dwyer, Chief, NRC Region I Medical Branch, informed you and other members of your staff that the NRC was considering escalated enforcement for two of the apparent violations. Mr. Dwyer also informed you that we had sufficient information regarding the apparent violations and CCMHC's corrective actions to make an enforcement decision without the need for a pre-decisional enforcement conference or a written response from you. Dan Berkley, CCMHC's Radiation Safety Officer subsequently informed Mr. Dwyer that CCMHC did not believe that a pre-decisional enforcement conference or written response was needed.

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

Therefore, based on the information developed during the inspection, 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 two most significant violations related to the aforementioned medical event. The first of these violations involved a brachytherapy implant performed on February 25, 2011, for which CCMHC did not adequately implement a written procedure, as required by 10 CFR 35.41(a)(2), resulting in 16 of the 63 prescribed palladium-103 seeds being implanted outside the planned treatment area. CCMHC's subsequent assessment of the implant did not identify that the delivered dose was different from the prescribed dose by more than 20 percent. This failure to identify the medical event contributed to the second violation which was CCMHC not notifying the NRC Operations Center by the next calendar day that a medical event had occurred. Instead, CCMHC reported the medical event on March 5, 2012, following NRC questioning during the onsite inspection. The failure to inform the NRC of a medical event no later than the next calendar day, in accordance with 10 CFR 35.3045(c), impacts the NRC's ability to promptly assess the event circumstances and respond to ensure that CCMHC had appropriate controls in place to ensure radiation safety during subsequent medical treatments. These two violations have been categorized collectively as a Severity Level (SL) III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a SL III problem. 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 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for CCMHC's corrective actions taken to address the violations. Specifically, CCMHC: (1) developed a detailed written policy specifically for prostate brachytherapy which includes procedures for seed verification, post-operative surveys, post implant dosimetry evaluations which include an independent review, and medical event identification and notification; and, (2) conducted training of its applicable staff upon implementation of these procedures. Therefore, in recognition of the absence of previous escalated enforcement action, and to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III problem constitutes an escalated enforcement action that may subject you to increased inspection effort.

Two additional violations, also documented in the Notice, have been categorized in accordance with the NRC Enforcement Policy at SL IV. These violations involved the failure by CCMHC to: (1) determine timer linearity over the typical range of use for the high dose rate remote afterloader; and, (2) secure from unauthorized removal or access, licensed materials that were in storage. The circumstances surrounding these additional violations are documented in detail in the aforementioned inspection report. The violations are being cited because they were identified by the NRC.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the

date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03003390/2012001, in your March 1, 2013, correspondence, and in this letter. Therefore, you are not required to respond to this letter 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, 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 and its enclosure 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 Website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at (http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

William M. Dean
Regional Administrator

Docket No. 03003390
License No. 47-09772-02

Enclosure:
Notice of Violation

cc w/enclosure:
Daniel Berkley, Radiation Safety Officer
State of West Virginia

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Sincerely,

/RA/

William M. Dean
Regional Administrator

Docket No. 03003390
License No. 47-09772-02

Enclosure:
Notice of Violation

cc w/enclosure:
Daniel Berkley, Radiation Safety Officer
State of West Virginia

Distribution: see next page **ADAMS ACCESSION NO. ML131220A356**

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DATE	7/19/13	7/25/13	7/25/13	7/29/13	7/30/13
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* See previous concurrence page ** HQ to perform a quick review

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NOTICE OF VIOLATION

Camden-Clark Memorial Hospital Corporation
Parkersburg, West Virginia

Docket No. 03003390
License No. 47-09772-02
EA-13-107

During an NRC inspection conducted between January 18, 2012, and April 22, 2013, (which included an on-site inspection as well as an in-office review of information provided by Camden-Clark Memorial Hospital Corporation (CCMHC)), for which an exit meeting was conducted on April 22, 2013, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

I. ESCALATED VIOLATIONS

A. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2) states, in part, that for any administration requiring a written directive, the license shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. 10 CFR 35.41(b)(2) requires, at a minimum, that the procedures verify that the administration is in accordance with the treatment plan and the written directive.

CCMHC implementing procedure for medical administrations, "Quality Assurance in Brachytherapy" Guideline, requires that a discrepancy of +/- 20% in the radiation dose delivered will be treated as a misadministration (medical event) and appropriate action will be taken to document and report such misadministration (medical event).

Contrary to the above, CCMHC did not implement its written procedure to provide high confidence that an administration was performed in accordance with the written directive. Specifically, on February 25, 2011, CCMHC implanted a patient with 63 palladium-103 seeds to deliver a D90 dose (the dose received by 90 percent of the prostate volume) of 125 Gy. During a post implant assessment on April 1, 2011, CCMHC did not identify that 16 of the 63 seeds were outside of the reasonably expanded planned treatment volume and the D90 dose was 66.6 Gy (i.e., that the delivered dose differed from the prescribed dose by greater than 20 percent), and did not take appropriate action to document and report the misadministration (medical event).

B. 10 CFR 35.3045 requires, in part, that the NRC Operations Center be notified by telephone no later than the next calendar day after the discovery of any event where the administered dose differs from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more.

Contrary to the above, CCMHC did not notify the NRC Operations Center by the next calendar day after discovering, during a review of post implant dosimetry plans on April 1, 2011, that a dose administered on February 25, 2011, differed from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue and the total dose differed by greater than 20 percent of the prescribed dose. This required notification by April 2, 2011, but CCMHC did not notify the NRC Operations Center until March 5, 2012.

These violations are categorized collectively as a Severity Level (SL) III problem (Enforcement Policy Examples 6.3 and 6.9).

II. NON-ESCALATED VIOLATIONS

A. 10 CFR 35.633(a) requires, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements following replacement of the source.

10 CFR 35.633(b)(5) requires, in part, that remote afterloader full calibration measurements include a determination of timer linearity over the typical range of use.

Contrary to the above, on November 16, 2011, CCMHC performed a high dose rate remote afterloader (HDR) full calibration measurement that did not include a determination of timer linearity over the typical range of use. Specifically, after source replacement, timer linearity was determined over a range of 0 to 15 seconds, when the typical range was 0.1 to 90 seconds.

This is a Severity Level IV violation (Enforcement Policy Example 6.3).

B. 10 CFR 20.1801 requires, in part, that the licensee secure from unauthorized removal or access licensed materials that are stored in a controlled area.

Contrary to the above, on January 18, 2012, CCMHC did not secure from unauthorized removal or access licensed materials that were stored in a controlled area. Specifically, greater than 100 millicuries of technetium-99m, 2 millicuries of germanium-68, 500 microcuries of cobalt-57, 100 microcuries of cesium-137, and 45 microcuries of barium-133 were stored in the CCMHC Nuclear Medicine Department Hot Lab, which was unlocked and unattended.

This is a Severity Level IV violation (Enforcement Policy Example 6.7).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03003390/2012001, in CCMHC's March 1, 2013, correspondence, and in this letter. Therefore, you are not required to respond to this Notice. 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-13-107," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 8th day of August, 2013