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

April 29, 2013

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

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

SUBJECT: NRC INSPECTION REPORT NO. 03003390/2012001, CAMDEN-CLARK MEMORIAL HOSPITAL CORPORATION, PARKERSBURG, WEST VIRGINIA

Dear Mr. McClure:

On January 18 and 19, 2012, Tara Weidner of this office conducted a safety inspection at Camden Clark Memorial Hospital Corporation. 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 selective examination of representative records. Preliminary findings of the inspection were discussed with your Radiation Safety Officer, Daniel Berkley, at the conclusion of the on-site inspection

Following the onsite inspection, you evaluated several prostate brachytherapy implants performed at Camden-Clarke and you identified one potential medical event. You reported this potential medical event to the NRC's Headquarters Operations Center on March 5, 2012. A NRC medical consultant reviewed the reported case and concluded it was a medical event. This NRC in-office review continued through April 22, 2013, and included: (1) an assessment of your 15-day written medical event report; (2) a review of the NRC medical consultant's report; and (3) the review of your proposed corrective and preventive actions described in your correspondence dated March 1, 2013. A final exit meeting was conducted telephonically with you and other members of your staff on April 22, 2013. Based on the result of this inspection, four apparent violations of NRC requirements were identified.

The apparent violations involved

1. The failure to secure from unauthorized removal or access licensed materials that were stored in a controlled area, as required by 10 CFR 20.1801;
2. The failure to determine high dose rate remote afterloader timer linearity over the typical range of use as required by 10 CFR 35.633(b)(5);
3. The failure to implement procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2); and
4. The failure to notify the NRC Operations Center of a medical event within 24 hours as required by 10 CFR 35.3045(c).

A more detailed description of the apparent violations and the circumstances surrounding the apparent violations may be found in the enclosed inspection report.

Because the NRC has not made a final determination in this matter with respect to the apparent violations, a Notice of Violation for these findings is not being issued at this time. You will be advised by separate correspondence when a final determination has been made.

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 document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select Nuclear Materials; Med, Ind, & Academic Uses; then Regulations, Guidance and Communications. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents; then Enforcement Policy (Under 'Related Information'). You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

No reply to this letter is required. Please contact Tara Weidner at (610)337-5272 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03003390/2012001

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

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Sincerely,
Original signed by James P. Dwyer
James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03003390/2012001
cc:
Daniel Berkley, Radiation Safety Officer
State of West Virginia
Distribution:
D. J. Holody, RI
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DATE				

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03003390/2012001
Docket No.	03003390
License No.	47-09772-02
NMED No.	120159
Licensee:	Camden-Clark Memorial Hospital Corporation
Location:	800 Garfield Avenue Parkersburg, West Virginia 26102
Locations Inspected:	705 and 800 Garfield Avenue, Parkersburg, West Virginia
Inspection Dates:	January 18-19, 2012 April 22, 2013 (telephonic exit meeting)
Date Follow-up Information Received:	February 15, 2012; March 5, 9, 19, 20, 2012; August 15, 2012; October 30, 2012; December 11, 2012; and March 1, 2013

Inspector: ***/RA James Dwyer for/*** ***4/29/13***

_____ _____

Tara L. Weidner — date
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/*** ***4/29/13***

_____ _____

James P. Dwyer, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Camden-Clark Memorial Hospital Corporation
NRC Inspection Report No. 03003390/2012001

A routine, unannounced inspection was conducted on January 18-19, 2012, at Camden Clark Memorial Hospital Corporation (CCMHC) in Parkersburg, West Virginia. Additional information provided by CCMHC on February 15, 2012; March 5, 9, 19, and 20, 2012; August 15, 2012; October 30, 2012; December 11, 2012; and March 1, 2013; was also reviewed. The inspection consisted of a review of licensed activities associated with the use of radioactive material in the CCMHC Nuclear Medicine and Radiation Oncology Departments. The inspector also reviewed records for 16 permanent prostate brachytherapy implants that occurred since the last inspection and requested that a medical consultant review 3 of the implants. In-office evaluation of the medical events, the medical consultant's report, and CCMHC's corrective actions continued through April 22, 2013. The medical consultant concluded that two of the three implants did not meet the American Society for Radiation Oncology (ASTRO) and NRC's Advisory committee for the Medical Use of Isotopes (ACMUI) definition of a medical event. However, the third implant revealed a number of seeds outside of the planned treatment volume (PTV) which resulted in a substantially underdosed prostate. The consultant concluded that the third implant met the ASTRO/ACMUI definition of a medical event, "since less than 80 percent of the source strength was within a reasonably expanded PTV."

Based on the results of this inspection, the inspector identified four apparent violations:

- CCMHC did not secure from unauthorized removal or access licensed materials that were stored in a controlled area, as required by 10 CFR 20.1801. Specifically, approximately 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 an unlocked and unattended hot lab.

- CCMHC did not include a determination of timer linearity over the typical range of use for the high dose rate remote afterloader (HDR) as required by 10 CFR 35.633(b)(5). Specifically, CCMHC only performed timer linearity between 0 seconds and 15 seconds when the typical range was between 0.1 seconds and 90 seconds.

- CCMHC did not implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, CCMHC's written procedures for brachytherapy stated that a discrepancy of +/- 20% in the radiation dose delivered would be treated as a misadministration and appropriate follow-up actions would be taken. However, CCMHC did not make an assessment to determine if the delivered dose was within 20 percent of the prescribed dose. As a result, a medical event was not identified by CCMHC.

- CCMHC did not notify the NRC Operations Center of a medical event in accordance with 10 CFR 35.3045(c). Specifically, CCMHC personnel had adequate information on April 1, 2011, the date of the post-implant imaging, to determine that a medical event had occurred on February 25, 2011. However, the NRC Operations Center was not notified until March 5, 2012.

REPORT DETAILS

1. Organization, Scope, and Management Oversight of the Program

a. Inspection Scope

A routine, unannounced inspection was conducted on January 18-19, 2012, at Camden Clark Memorial Hospital Corporation (CCMHC) in Parkersburg, West Virginia. Additional information provided by CCMHC on February 15, 2012; March 5, 9, 19, 20, 2012; August 15, 2012; October 30, 2012; December 11, 2012; and March 1, 2013, were reviewed. The inspection was performed in accordance with NRC Inspection Procedure 87131 and 87132 and consisted of a review of licensed activities associated with the use of byproduct material in the Nuclear Medicine and Radiation Oncology Departments. The following focus areas were reviewed during the inspection: security and control of licensed material; shielding of licensed material; comprehensive safety measures; radiation dosimetry program; radiation instrumentation and surveys; radiation safety training and practices; and management oversight.

The inspector also reviewed 16 permanent prostate brachytherapy implants that occurred between January 2009 and January 2012. Resulting from this review, CCMHC reported a potential medical event to the NRC Operations Center on March 5, 2012 (NRC Event Notification No. 47719). The assistance of a medical consultant was retained and a report was issued on September 11, 2012.

The inspector toured CCMHC facilities, conducted interviews with CCMHC personnel, observed day-to-day operations, and reviewed documents and procedures. In addition, an in-office review to evaluate the potential medical event, the medical consultant's report, and CCMHC's corrective actions continued through April 22, 2013.

b. Observations and Findings

Licensed Material Program Organization and Scope

CCMHC is a medical institution authorized for the possession and use of radionuclides permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600. A cesium-137 sealed source is also authorized for instrument calibration. The Radiation Safety Officer (RSO) is a consultant diagnostic physicist who is on-site 2 days each week and is responsible for auditing the radiation safety program. The consultant audits were noted to focus primarily on the Nuclear Medicine Department with limited review of the Radiation Oncology Department activities. Discussions with the consultant RSO indicated that he would include additional oversight of the Radiation Oncology program in future audits.

Nuclear Medicine

The CCMHC Nuclear Medicine program includes a full range of diagnostic procedures in accordance with 10 CFR 35.100, 35.200, and 35.300 diagnostic studies. Two full-time Nuclear Medicine Technologists (NMTs) and one part-time NMT conduct approximately nine general nuclear medicine studies and eight positron emission tomography (PET)

studies daily. All studies are performed under the supervision of 6 authorized users (AU). Unit dosages and iodine-131 capsules are received from Pharmalogic-Clarksburg and are used for 99 percent of the studies. Bulk technetium-99m is available for emergent studies (evenings and weekends). Unit dosages of fluorine-18 fluorodeoxyglucose (F-18 FDG) are provided by IBA Molecular-Morgantown. Dosages are assayed in a dose calibrator prior to administration. The majority of studies are hepatobiliary, bone, lung, renal, gastric emptying, sentinel node biopsies, and thyroid uptake scans. Cardiac imaging is primarily done at St. Joseph's Medical Center, which was recently acquired by CCMHC.

Upon arriving in the Nuclear Medicine Department, the inspector observed that the hot lab was unsecured and unattended. At that time, approximately 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 within the hot lab. 10 CFR 20.1801 requires, in part, that a licensee secure from unauthorized removal or access licensed materials that are stored in a controlled area. Contrary to this requirement, licensed materials stored in a controlled area were not secured from unauthorized removal or access. This is an apparent violation of 10 CFR 20.1801. As a result of this finding, the Nuclear Medicine Department hot lab was secured and the Director of Radiology verbally counseled the Nuclear Medicine staff and followed up with a written mandate requiring that byproduct material be secured when not attended.

Radiation Oncology

The CCMHC Radiation Oncology program includes uses permitted by 10 CFR 35.300, 35.400, and 35.600. Radiation Oncology is staffed with 2 AUs and one authorized medical physicist (AMP) who perform iodine-131 therapies, permanent prostate brachytherapies, and HDR treatments, primarily for gynecologic cancers.

Iodine-131 therapies are performed approximately 3 times per year by the Radiation Oncology Department. I-131 capsules are received and assayed by the Nuclear Medicine Department and transferred to Radiation Oncology by the dosimetrist. Prior to dose administration, the AU prepares the written directive and counsels the patient on radiation safety. All therapy treatments are performed on an outpatient basis with the AU, RSO and dosimetrist present at the administration. Patient specific calculations are completed and the patient is provided with written instructions prior to being released.

CCMHC began HDR therapy operations in April 2011. They possess a Nucletron microSelectron Model 106.990 V3 HDR, which is used primarily for gynecologic treatments. Mammosite, bronchial, and lung treatments are performed as well. The inspector observed the CCMHC personnel responsible for HDR operations perform daily spot checks and a patient treatment. The inspector reviewed records for HDR full calibration measurements, and noted that, in general, the CCMHC AMP was performing full calibration measurements as required by 10 CFR 35.633. However, the determination of the HDR timer linearity was not being performed over the typical range of use. According to Nucletron, the Model 106.990 V3 has 2 independent timer circuits that are separate both functionally and physically to measure dwell time and total time.

Therefore, according to Nucletron, for timer linearity determinations, the typical range of use is the maximum dwell time. CCMHC determined timer linearity out to a dwell time of 15 seconds however, the typical dwell times (range of use) range from 0.1 to 90 seconds. 10 CFR 35.633(b) requires, in part, full calibrations measurements must include determination of timer accuracy and linearity over the typical range of use. Contrary to this requirement, timer linearity was only performed between 0 seconds and 15 seconds when the typical range was between 0.1 seconds and 90 seconds. This is an apparent violation of 10 CFR 35.633(b). As a result of this finding, CCMHC verified timer linearity up to 90 seconds and revised their HDR Quarterly QA procedure to require verification of timer linearity over the full capacity of the HDR unit up to 90 seconds or the longest clinical dwell time.

CCMHC performs approximately 5 prostate brachytherapy procedures per year using palladium-103 and iodine-125 seeds. Following implantation of the seeds, a dose rate survey is performed and patients are released based on the measured dose rate at one meter. In general, CCMHC utilizes the following process to perform prostate brachytherapy treatments: (1) prior to treatment, the urologist obtains ultrasound images of the patient's prostate gland to assess the prostate volume and the AU specifies margins around the prostate to define a planning treatment volume (PTV); (2) the AU develops a computerized treatment plan (pre-treatment plan) based on the information received from the urologist; (3) the AU prepares and signs the written directive for the implant which designates the implant site, radioisotope, number of seeds, activity of seeds, and prescribed dose; and (4) the seeds are ordered from an authorized vendor by the AU or person designated by AU to order seeds. During the implant procedure, the implant team utilizes ultrasound imaging to visualize the implantation of the seeds into the prostate. Approximately 30 days following the implant, the patient returns for post-implant computerized tomography (CT) imaging. Information obtained is used to develop the post-plan dosimetric evaluation of the implant. The AU is responsible for generating the post-implant dosimetry and evaluating the adequacy of the implant.

10 CFR 35.41(a)(2) requires, for any administration requiring a written directive, that the licensee develop, implement, and maintain written procedures to provide high confidence that, in part, each administration is in accordance with the written directive. 10 CFR 35.41(b)(2) requires, at a minimum, that the procedure verify that the administration is in accordance with the treatment plan and the written directive. CCMHC's procedure entitled, "Quality Assurance in Brachytherapy," indicates that, "A discrepancy of plus/minus 20 percent in the radiation dose delivered will be treated as a misadministration1. Appropriate action will be taken to document and report such misadministrations. Appropriate follow-up action will be taken to correct and prevent future incidents."

The inspector reviewed documentation of 16 prostate brachytherapy implant cases. During the review of the post-treatment plans, the inspector noted that the D90 values (the dose received by 90 percent of the prostate volume) in 3 cases, were less than 80 percent of the prescribed amounts. These results suggested that the treatments were not performed in accordance with CCMHC's acceptance criteria; however, the inspector

1 NRC regulations now refer to a misadministration as a medical event.

noted that CCMHC did not make assessments to determine if the delivered dose, in each case, was within 20 percent of the prescribed dose. CCMHC did not implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, CCMHC's written procedures for brachytherapy stated that a discrepancy of +/- 20 percent in the radiation dose delivered will be treated as a misadministration and appropriate follow-up actions would be taken. However, CCMHC did not make an assessment to determine if the delivered dose was within 20 percent of the prescribed dose. As a result, a medical event was not identified by CCMHC. Failure of the licensee to make assessments to determine if the delivered dose is within 20 percent of the prescribed dose is an apparent violation of 10 CFR 35.41(a)(2)..

Medical Event Reporting & Follow-up

Following identification by the inspector of the 3 cases where D90 values were less than 80 percent of the prescribed amounts, CCMHC performed assessments of the cases and reported, as a medical event, one implant performed on February 25, 2011. On March 5, 2012, CCMHC reported the medical event to the NRC Operations Center (NRC Event Notification No. 47719).

10 CFR 35.3045(a) requires, in part, a licensee shall report any event in which the administration of radiation from byproduct material results in a dose that differs from the prescribed dose by more than 5 rem effective dose equivalent or 50 rem to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more. 10 CFR 35.3045(c) requires the licensee to notify, by telephone, the NRC Operations Center no later than the next calendar day after the discovery of the medical event. The inspector concluded that the post implant CT performed on April 1, 2011, and the information previously on file associated with the patient's treatment plan, provided the licensee with the information needed to determine that a medical event occurred during the February 25, 2011 implant, still the licensee did not make the required notification to the NRC Operations Center until prompted by NRC on March 5, 2012. This is an apparent violation of 10 CFR 35.3045(c).

A 15-day report was received by NRC on March 8, 2012. CCMHC concluded in the 15-day report that the cause of the medical event was seed migration during and after the procedure.

The services of a medical consultant were obtained to review the three implants with D90s of less than 80 percent to determine if medical events occurred. According to the American Society for Radiation Oncology (ASTRO) and the NRC's Advisory Committee for the Medical Use of Isotopes (ACMUI), a medical event occurred if 20 percent or more of the source strength, documented in the written directive, is located outside of the reasonably expanded PTV. The medical consultant concluded that two of the three implants did not meet the ASTRO/ACMUI definition of a medical event. Specifically, in one case, 7 of the source strength was located outside of the reasonably expanded PTV and, in the second case, 12 percent of the source strength was located outside of the reasonably expanded PTV. The medical consultant concluded that the post implant

CT for the third implant, the implant performed on February 25, 2011, showed 25.4% of the

source strength outside of the reasonably expanded PTV and was therefore a medicalevent. According to the consultant, there was a substantial portion of the posterior prostate that was severely underdosed as there were few seeds in the posterior prostate and that the underdose could not be explained by prostate edema or seed migration alone. Specifically, in order for seed migration to be the cause of the medical event, a number of seeds would have had to migrate all in the same direction away from the posterior prostate.

As a result of the inspection, CCMHC developed a detailed written policy specifically for prostate brachytherapy which includes procedures for:

1. seed verification,
2. post operative surveys,
3. post implant dosimetry evaluations, which include;
   a. an independent review by a second radiation oncologist,
   b. criteria to determine implant quality, and
   c. timeframe for post implant review,
4. medical event identification and notification.

c. Conclusions

Based on the inspector's observations, four apparent violations of NRC requirements were identified. Specifically:

- CCMHC did not secure, from unauthorized removal or access, licensed materials that were stored in a controlled area, as required by 10 CFR 20.1801. Specifically, approximately 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 an unlocked and unattended Nuclear Medicine Department hot lab.

- CCMHC did not include a determination of timer linearity over the typical range of use for the HDR, as required by 10 CFR 35.633(b). Specifically, CCMHC only performed timer linearity between 0 seconds and 15 seconds when the typical range was between 0.1 seconds and 90 seconds.

- CCMHC did not implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, CCMHC's written procedures for brachytherapy stated that a discrepancy of +/- 20 percent in the radiation dose delivered will be treated as a misadministration and appropriate follow-up actions would be taken. However, CCMHC did not make an assessment to determine if the delivered dose was within 20% of the prescribed dose. As a result, a medical event was not identified by CCMHC.

- CCMHC did not notify the NRC Operations Center of a medical event in accordance with 10 CFR 35.3045(c). Specifically, CCMHC personnel had adequate information on April 1, 2011, the date of the post-implant CT, to determine that a medical event had occurred on February 25, 2011. However, the NRC Operations Center was not notified until March 5, 2012.

2. Exit Meeting

A preliminary exit meeting was conducted on January 19, 2012, to discuss the scope of the inspection and the inspector's initial observations. On April 22, 2013 an exit meeting was held by telephone with David McClure, Vice President of Operations, and other members of CCMHC's staff, to discuss the results of this inspection and the medical consultant's report.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

*+ Daniel Berkley – Radiation Safety Officer
+ Joshua Hayes – Authorized Medical Physicist
Michael Galloway, M.D. – Authorized User
Gabor Altdorfer, M.D. – Authorized User
Paul Frey - Nuclear Medicine Technologist
Kim Radcliffe - Nuclear Medicine Technologist
Teresa Cutlip – Dosimetrist
*+ Terri Richards - Manager, Radiology
*+ Reinne Leavitt – Manager, Radiation Oncology
* Thomas Heller – Vice President, Operations
+ David McClure – Vice President, Operations

* Present at preliminary exit meeting on January 19, 2012
+ Participated in telephonic exit meeting conducted on April 22, 2013