

January 21, 2010

EA-09-040
NMED No. 080896

Tracy Kemp Stallings
Chief Operating Officer
Chippenham and Johnston-Willis Hospitals, Inc.
d/b/a CJW Medical Center - Johnston-Willis Campus
1401 Johnston-Willis Drive
Richmond, VA 23235

SUBJECT: NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03008805/2008003

Dear Ms. Kemp Stallings:

This letter refers to the NRC special inspection conducted on December 18, 2008, at Chippenham and Johnston-Willis (CJW) Medical Center – Johnston-Willis Campus in Richmond, Virginia. The special inspection reviewed the circumstances surrounding a medical event involving a gamma stereotactic radiosurgery treatment performed on December 16, 2008, in which the medical treatment provided to a patient was delivered to an incorrect site. CJW reported the medical event to the NRC Headquarters Operations Center on December 17, 2008. In addition to the on-site review, the inspection also involved consideration of: 1) additional information provided by CJW in correspondence dated December 29, 2008, and November 10, 2009; and 2) the findings by a medical consultant retained by the NRC to review this event, as documented in the consultant's October 29, 2009 report.

Penny Lanzisera and Marc Ferdas of the NRC conducted an inspection exit meeting with you and members of your staff by telephone on November 30, 2009, and informed you that the NRC was considering escalated enforcement for an apparent violation identified during the inspection. During that conversation, Mr. Ferdas also informed you that, while the NRC had sufficient information regarding the apparent violation and CJW's corrective actions to make an enforcement decision, CJW had the opportunity to attend a predecisional enforcement conference (PEC) or provide an additional written response. You informed Mr. Ferdas that CJW did not desire a PEC, and did not intend to provide an additional written response. The NRC issued the inspection report related to this action on December 14, 2009.

Based on the information developed during the inspection, including the information that CJW provided in its correspondence referenced above, as well as the NRC medical consultant's report, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. This violation involved the failure to develop, implement, and maintain written procedures to provide high confidence that each administration of radioactive material is in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, the licensee's written procedures did not provide high confidence for gamma stereotactic radiosurgery treatments because they did not require verification of the

treatment site (e.g., patient's left or right side) nor resolution of any inconsistencies in the written directive prior to administration of the dose. This resulted in the medical event on December 16, 2008, in that the patient received a dose to the left trigeminal nerve, an organ and tissue other than the intended treatment site, and that dose exceeded the expected dose, as defined in the written directive, by 50 rem and 50 percent or more (10 CFR 35.3045(a)(3)). CJW indicated that no adverse effects to the patient have been reported to them, and the NRC's medical consultant agreed with CJW's assessment of potential patient side effects.

The NRC understands that CJW identified the misadministration immediately after it occurred, and informed the patient, who elected to receive an additional treatment to the originally-intended site (right trigeminal nerve) that same day. However, the failure to have adequate procedures that verified the location of treatment sites to ensure the administration is in accordance with the written directive resulted in the medical event, and also necessitated the second treatment, which resulted in additional exposure to radiation. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because CJW has not been the subject of escalated enforcement actions within the last two years, or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The NRC determined that corrective action credit is warranted, because CJW's actions were considered to have been prompt and comprehensive. These actions included performing a comprehensive review of the medical event and revising CJW's policies and procedures related to verification of the treatment site. The revisions included the incorporation of independent verification of the treatment site by the radiation oncologist and neurosurgeon with confirmation by a nurse, as well as the involvement of the patient or the patient's authorized representative. Further, CJW's corrective actions included using a single piece of documentation that will accompany the patient through the entire course of treatment as the primary source of documentation to identify the treatment site, since the use of both the written directive and treatment log contributed to this event.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, 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 violation constitutes an escalated enforcement action that may subject CJW to increased inspection effort.

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 this letter, in Inspection Report No. 03008805/2008003, dated December 14, 2009, and in the referenced CJW correspondences. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect CJW's 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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>. To the extent possible, CJW's response 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 the response that identifies the information that should be protected and a redacted copy of the response that deletes such information. If you request withholding of such information, you must specifically identify the portions of the 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/

Samuel J. Collins
Regional Administrator

Docket No. 030-08805
License No. 45-15249-01

Enclosure: Notice of Violation

cc: Commonwealth of Virginia

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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>. To the extent possible, CJW's response 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 the response that identifies the information that should be protected and a redacted copy of the response that deletes such information. If you request withholding of such information, you must specifically identify the portions of the 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/

Samuel J. Collins
Regional Administrator

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Enclosure: Notice of Violation

cc: Commonwealth of Virginia

Distribution: see next page

SUNSI Review Complete: MMM (Reviewer's Initials)

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NOTICE OF VIOLATION

Chippenham and Johnston-Willis Hospitals, Inc.
d/b/a CJW Medical Center - Johnston-Willis Campus
Richmond, Virginia

Docket No. 030-08805
License No. 45-15249-01
EA-09-040

During an NRC inspection conducted between December 18, 2008 and November 30, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, as of December 16, 2008, Chippenham and Johnston-Willis Hospitals, Inc – d/b/a CJW Medical Center – Johnston-Willis Campus (CJW) did not develop, implement, and maintain procedures for gamma stereotactic radiosurgery, an administration requiring a written directive, to provide high confidence that each administration is in accordance with the written directive. Specifically, CJW's procedures did not require verification of the treatment site nor resolution of any inconsistencies in the written directive prior to administration of the dose. This resulted in a patient receiving treatment to the left trigeminal nerve instead of to the originally-intended site (right trigeminal nerve).

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03008805/2008003, dated December 14, 2009, and in the CJW correspondences dated December 29, 2008, and November 10, 2009. Therefore, CJW is not required to respond to this Notice of Violation (Notice). However, CJW is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect CJW's corrective actions or position. In that case, or if CJW chooses to respond, clearly mark the response as a "Reply to a Notice of Violation, EA-09-040," 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, 475 Allendale Rd., King of Prussia, PA, 19406, within 30 days of the date of the letter transmitting this Notice.

If CJW chooses to respond, the 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, CJW may be required to post this Notice within two working days.

Dated this 21st day of January 2010