

January 6, 2010

EA-09-266
NMED Nos. 090691, 090692

Ms. Jacalyn Liebowitz
Vice President, Patient Care Continuum
Allegiance Health
205 N. East Avenue
Jackson, Michigan 49201

SUBJECT: NOTICE OF VIOLATION – ALLEGIANCE HEALTH; NRC INSPECTION
REPORT NO. 030-01990/2009-001(DNMS)

Dear Ms. Liebowitz:

This refers to the inspection conducted on September 9, 2009, at your facility located in Jackson, Michigan, with continuing in-office review through October 8, 2009. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for two medical events that occurred on April 16, 2009, that your staff discovered during post-implant dosimetry analysis conducted in August 2009. During the inspection, an apparent violation of U.S. Nuclear Regulatory Commission (NRC) requirements was identified by the NRC inspector. Details regarding the apparent violation were provided to you in NRC Inspection Report No. 030-01990/2009-001(DNMS), dated October 26, 2009.

In the letter transmitting the inspection report, we offered you the opportunity to address the apparent violation identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. In a letter dated December 10, 2009, you provided a response to the apparent violation which outlined your corrective actions.

Based on the information developed during the inspection and the information that you provided in your December 10, 2009, response to the inspection 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. The violation involved the failure to develop adequate written procedures to provide high confidence that each prostate seed implant was in accordance with the written directive as required by Title 10 of the Code of Federal Regulations (10 CFR) 35.41. The NRC determined that the root cause of the violation was a belief that the patients' prostate volume was adequately determined during the treatment planning session such that additional verification was not necessary, even though more than three weeks elapsed between when the treatment was planned and when it was performed.

The violation is of concern to the NRC because the failure to have an adequate procedure to ensure that the prostate seed implants were in accordance with the written directive resulted in two medical events. One patient required a second treatment, which resulted in an additional exposure to radiation. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy. As an immediate corrective action, you temporarily suspended the brachytherapy program. As a long term corrective action to prevent recurrence, you revised your procedures to require that: (1) the procedure date be established prior to performing the pre-treatment plan, in order to minimize the potential changes to the prostate volume; (2) prior to implanting the patient with radioactive material, the Authorized User must verify the prostate volume; (3) during the implant procedure, the Authorized User must use appropriate imaging modalities (including bi-planar ultrasound and/or fluoroscopy) to ensure that the patient's prostate is still localized correctly and the seeds are placed in the intended positions in the prostate; and (4) the Authorized User performing seed implants must have documented experience in successfully performing prostate seed implants within the past 18 months, or have documented training in the performance of the prostate seed implants within the past 18 months. The NRC determined that these corrective actions were adequate.

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 Severity Level III violation constitutes escalated enforcement action that may subject you 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 to prevent recurrence, and the date when full compliance was achieved was already adequately addressed on the docket in the inspection report dated October 26, 2009, and in your reply dated December 10, 2009. 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, 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

J. Liebowitz

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Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-01990
License No. 21-00258-06

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

Letter to Jacalyn Liebowitz from Mark A. Satorius dated January 6, 2010

SUBJECT: NOTICE OF VIOLATION – ALLEGIANCE HEALTH;
NRC INSPECTION REPORT NO. 030-01990/2009-001(DNMS)

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NOTICE OF VIOLATION

Allegiance Health
Jackson, Michigan

Docket No. 030-01990
License No. 21-00258-06
EA-09-266

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 9, 2009, with continuing review through October 8, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR), Section 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Title 10 CFR 35.41(b)(2), requires, as a minimum, that the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, on April 16, 2009, the licensee did not develop written procedures to provide high confidence that the administration was in accordance with the written directive. Specifically, the licensee's procedures did not contain any steps to ensure that no changes had occurred in the patients' prostate volume between the time the treatment plan was prepared and the administration of the treatment and no other method was provided to ensure that the administration was in accordance with the written directive. As a result, two medical events occurred.

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 to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-01990/2009-001(DNMS), dated October 26, 2009, and in a letter from the licensee dated December 10, 2009. 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-09-266," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, 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, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

ENCLOSURE

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 Agencywide Documents Access and Management 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.

Dated this 6th day of January 2010

Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-01990
License No. 21-00258-06

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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1. OE concurrence received via e-mail from K. Day on December 30, 2009.