



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

April 21, 2016

EA-15-251

Greg Haar, Administrator
Siouxland Urology Center, LLC
455 Sioux Point Road
Dakota Dunes, SD 57049

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-36922/2015-001

Dear Mr. Haar:

This letter refers to the routine, unannounced inspection conducted on June 15, 2015, at the Siouxland Urology Center located in Dakota Dunes, South Dakota. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. A final exit briefing was conducted telephonically with Dr. Gregory Naden, Cheryl Porter, and Dr. Jason Spaans on January 20, 2016. Based on the results of the inspection, one apparent violation was identified. The apparent violation was described in the subject inspection report, dated January 29, 2016 (Agencywide Documents Access and Management System (ADAMS) ML16019A495).

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation by attending a predecisional enforcement conference, requesting alternative dispute resolution, or by providing a written response before we made our final enforcement decision. In a letter dated March 2, 2016, your contracted medical physicist, Dr. Jason Spaans, provided a response to the apparent violation. On March 3, 2016, members of my staff spoke with you and members of your staff telephonically regarding the response. In a letter dated March 8, 2016, you provided a supplemental written response to the apparent violation.

Based on the information developed during the inspection and information that you provided in your responses 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 January 29, 2016, letter and enclosed inspection report. The violation concerned the failure to ensure that written directives were dated and signed by an authorized user before the administration of therapeutic doses of radiation from byproduct material. Twenty-eight written directives from February 2013 to June 2015 were reviewed during the inspection, and in each case it was found that written directives were not dated and signed by an authorized user prior to the manual brachytherapy procedures.

The NRC attributed the violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40 to several causal factors: (1) there was a tendency and practice of informal communication from the authorized user to the medical physicists, (2) the written directive form was not being

signed or filled out by the authorized user until after the procedure was completed, and (3) the procedure to perform manual brachytherapy did not address the need for pre-implantation and post-implantation written directives nor the information required by regulation to be included in written directives.

The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The NRC Enforcement Policy, in Section 6.3.c.2, discusses an example of a Severity Level III violation for written directives. This example includes a programmatic failure to implement written directives or procedures for administrations requiring a written directive to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41. Based on the review of 28 separate manual brachytherapy procedures and associated written directives, the NRC has concluded that the failure to have an authorized user sign and date a written directive for these cases prior to administration constitutes a programmatic failure. No medical events or other actual consequences were identified as a result of this programmatic failure, however a significant potential existed for such consequences to result from this failure. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty of \$3,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last 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. Your written responses included revising the prostate seed implant procedures and associated forms, and retraining of the appropriate personnel. Together these actions adequately address the noncompliance. The NRC will review your implementation of these corrective actions during a future inspection.

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: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the letters dated March 2 and March 8, 2016. 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 "Agency Rules of Practice and Procedure," 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 and in ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary 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/>.

Should you have any questions regarding this letter or the enclosed Notice, please contact Mark R. Shaffer, Director, Division of Nuclear Materials Safety at 817-200-1106.

Sincerely,

/RA/

Kriss M. Kennedy
Deputy Regional Administrator

Docket: 030-36922
License: 40-34223-01

Enclosure: Notice of Violation

cc w/enclosure:
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Office of Health Care Facilities
Licensure and Certification
615 East 4th Street
Pierre, SD 57501-1700

Angela Leek, Chief
Bureau of Radiological Health
Iowa Dept. of Public Health
Lucas State Office Building, 5th Fl.
321 East 12th Street
Des Moines, IA 50319

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Sincerely,

/RA/

Kriss M. Kennedy
Deputy Regional Administrator

Docket: 030-36922
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cc w/enclosure:
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Office of Health Care Facilities
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Letter to Greg Haar from Kriss Kennedy dated April 21, 2016

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NOTICE OF VIOLATION

Siouxland Urology Center, LLC
Dakota Dunes, SD

Docket: 030-36922
License: 40-34223-01
EA-15-251

During an NRC inspection conducted on June 15, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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

10 CFR 35.40(b)(6) requires, in part, that the written directive must contain the patient or human research subject's name and for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) before implantation: treatment site, the radionuclide, and dose, and (ii) after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Contrary to the above, from February 14, 2013, to June 15, 2015, the licensee failed to ensure that written directives were dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material and that written directives contained the information required by 10 CFR 35.40(b)(6). Specifically, for 28 administrations of therapeutic doses of radiation from byproduct material, written directives were not dated and signed by an authorized user before the administration, and written directives prepared before implantation did not contain the radionuclide and dose.

This is a Severity Level III Violation (Section 6.3.c.2).

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 the letters dated March 2, 2016, and March 8, 2016. 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-15-251," 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 IV, 1600 E. Lamar Blvd., Arlington, TX 76011-4511, within 30 days of the date of the letter transmitting this Notice of Violation.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 or proprietary information so that it can be made available to the Public without redaction.

Dated this 21st day of April 2016

Enclosure