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

March 23, 2016

EA-16-036

Ms. Lisa Van Heek
Interim Vice President of Patient Care Services
Avera Sacred Heart Hospital
501 Summit Street
Yankton, SD 57078-3899

SUBJECT: NRC INSPECTION REPORT 030-03235/2016-001 AND NOTICE OF VIOLATION

Dear Ms. Van Heek:

This letter refers to the routine, unannounced inspection conducted on January 28, 2016, at your facility in Yankton, South Dakota. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. On January 28, 2016, at the conclusion of the onsite portion of the inspection, the inspectors discussed the preliminary inspection findings with the hospital staff and management. A final exit briefing was conducted telephonically with you, Dr. Prasad, and other members of your staff March 17, 2016.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. 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 violation involved the failure to prepare written directives that contained all of the information required by 10 CFR 35.40. The violation is being cited in the enclosed Notice of Violation (Notice) because the NRC identified the violation during the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful. You can find the Information Notice on the NRC website at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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, 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. 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.

Should you have any questions regarding this letter or the enclosed Notice, please contact Janine F. Katanic, PhD, CHP, at 817-200-1151 or the undersigned at 817-200-1191.

Sincerely,

/RA by JLThompson Acting For

Ray L. Kellar, P.E., Chief
Nuclear Materials Safety Branch A
Division of Nuclear Materials Safety

Docket No: 030-03235
License No: 40-01683-01

Enclosure:
Notice of Violation (Notice)

cc: State of South Dakota, Radiation Control Program Director

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cc: State of South Dakota, Radiation Control Program Director

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X SUNSI Review By: **JEV**	ADAMS X Yes ☐ No	X Publicly Available ☐ Non-Publicly Available	X Non-Sensitive ☐ Sensitive	Keyword: N/A

OFFICE	RIV:DNMS	RIV:DNMS	ATL:ACES	C:NMSB-A	
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DATE	03/17/16	03/17/16	03/23/16	03/23/16	

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NOTICE OF VIOLATION

Avera Sacred Heart Hospital
Yankton, South Dakota

Docket No: 030-03235
License No: 40-01683-01
EA-16-036

During an NRC inspection conducted on January 28, 2016, one 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 sodium iodide I-131 greater than 30 microcuries and any therapeutic dosage of unsealed byproduct material.
>
> 10 CFR 35.40(b)(1) requires, in part, that a written directive must contain the patient or human research subject's name, and for any administration of quantities greater than 30 microcuries of sodium iodide I-131, the dosage.
>
> 10 CFR 35.40(b)(2) requires, in part, that a written directive must contain, for a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131, the radioactive drug, the dosage, and the route of administration.
>
> Contrary to the above, between March 1, 2013 and January 28, 2016, the licensee failed to ensure that written directives were dated prior to administrations of sodium iodide I-131 greater than 30 microcuries and that written directives for therapeutic dosages of unsealed byproduct material other than sodium iodide I-131 contained the dosage and route of administration. Specifically: four written directives prepared for sodium iodide I-131 administrations greater than 30 microcuries were not dated by an authorized user prior to administration; one written directive prepared for a therapeutic administration of unsealed Sm-153 was not dated by an authorized user prior to administration and did not include the dosage; and three written directives prepared for therapeutic administrations of unsealed Ra-223 did not include the dosage or route of administration.
>
> This is a Severity Level IV violation (Section 6.3.d).

Pursuant to the provisions of 10 CFR 2.201, Avera Sacred Heart Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-16-036" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Enclosure

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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. 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, then 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 material, 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).

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

Dated this 23rd day of March 2016