



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

May 2, 2017

Mr. Dan Sullivan  
Vice President of Support Services  
St. Peter's Hospital  
2475 Broadway  
Helena, MT 59601

SUBJECT: NRC INSPECTION REPORT 030-10917/2017-001 AND NOTICE OF VIOLATION

Dear Mr. Sullivan:

This letter refers to the routine, unannounced inspection conducted on March 15, 2017, at your facility in Helena, Montana. 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 and facilities, independent radiation measurements, and interviews with personnel. At the conclusion of the onsite portion of the inspection, the preliminary inspection findings were discussed with you, Mr. Patrick Burns, Diagnostic Imaging Director, and Dr. Jefferson Fairbanks, Radiation Safety Officer. A final telephonic exit briefing was conducted with Dr. Fairbanks on May 1, 2017.

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, which can be found at the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited and described in the enclosed Notice of Violation (Notice). The violation is being cited in the enclosed Notice because it was identified by the NRC during the inspection. The violation involved the failure to ensure that two written directives were properly prepared and completed for administrations of a therapeutic dose of radiation from byproduct material. The NRC's review determined that this failure was isolated and did not represent a programmatic weakness in the manual brachytherapy program.

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 in preparing your response. You can find the Information Notice on the NRC website at: <http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. 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 817-200-1455.

Sincerely,

***/RA by JLThompson Acting For/***

Vivian H. Campbell, Chief  
Materials Licensing and Inspection Branch  
Division of Nuclear Materials Safety

Docket: 030-10917  
License: 25-12453-02

Enclosure:  
Notice of Violation

cc w/ enclosure:  
Brian Watson, Quality Assurance Division, DHHS

NRC INSPECTION REPORT 030-10917/2017-001 AND NOTICE OF VIOLATION DATED  
May 2, 2017.**DISTRIBUTION:**

S. Morris, DRA  
M. Shaffer, D/DNMS  
L. Howell, DD/DNMS  
R4DNMS\_MLIB

ADAMS ACCESSION NUMBER: ML17121A334

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NAME	JFKatanic	VHCampbell			
SIGNATURE	<i>/RA/</i>	<i>/RA by JLThompson Acting For/</i>			
DATE	05/01/17	05/02/17			

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## NOTICE OF VIOLATION

St. Peter's Hospital  
Helena, Montana

Docket No. 030-10917  
License No. 25-12453-02

During an NRC inspection conducted on March 15, 2017, 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 a written directive must 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)(ii) requires, in part, that the written directive must contain, 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, on April 13, 2015, and July 18, 2016, 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 after implantation but before completion of the procedure, the written directive contained the number of sources, and total source strength and exposure time (or the total dose). Specifically, for administrations of therapeutic doses of radiation from byproduct material from manual permanent implant brachytherapy: (1) On April 13, 2015, after implantation but before completion of the procedure, the written directive did not contain the number of sources, and total source strength and exposure time (or the total dose); and (2) On July 18, 2016, the written directive was not dated and signed by an authorized user before the administration of a therapeutic dose of radiation from byproduct material.

This is a Severity Level IV Violation (Section 6.3.d)

Pursuant to the provisions of 10 CFR 2.201, St. Peter's 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, 1600 E. Lamar Blvd., Arlington, Texas 76011, 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" 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.

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, Washington, DC 20555-0001.

Enclosure

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 2nd day of May 2017