

NRC FORM 591M
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: St. Peter's Hospital Remote Inspection of: (1) 2475 Broadway, and (2) 2550 Broadway, Helena, Montana. REPORT NO.: 030-10917 / 2021-001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region IV, 1600 East Lamar Blvd. Arlington, Texas 76011-4511	
3. DOCKET NUMBER 030-10917	4. LICENSE NUMBER 25-12453-01	5. DATE(S) OF INSPECTION February 19 - March 24, 2021	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

1. Based on the inspection findings, no violations were identified.
2. Previous violation(s) closed. (IR 030-10917 / 2017-001)
3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.
- Non-Cited Violation(s) was/were discussed involving the following requirement(s):
4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

Violation No. 1:


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 I-131 sodium iodide greater than 1.11 megabecquerels (MBq)(30 microcuries).

Contrary to the above, from at least July 1, 2020, through January 27, 2021, the licensee failed to have a written directive dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq)(30 microcuries). Specifically, the licensee maintained a practice where the nuclear medicine technologist completed the written directives for Iodine-131 administrations (of greater than 30 microcuries), including the "date" field, while the authorized user only signed the form. The licensee immediately corrected this practice and committed to ensuring the authorized user both signed and dated the written directive.

(Continued)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE	Steven Matthes		4.5.21
NRC INSPECTOR	Jason vonEhr	Jason E. VonEhr <small>Digitally signed by Jason E. VonEhr Date: 2021.03.29 12:19:49 -04'00'</small>	March 29, 2021
BRANCH CHIEF	Lizette Roldan-Otero	Lizette Roldan-Otero <small>Digitally signed by Lizette Roldan-Otero Date: 2021.05.05 07:58:24 -05'00'</small>	May 5, 2021

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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Violation No. 2:
10 CFR 35.41(a) requires, in part, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b) requires that, at a minimum, the procedures required by 10 CFR 35.41(a) must address the following items that are applicable to the licensee's use of byproduct material:

- (1) Verifying the identity of the patient or human research subject;
- (2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- (3) Checking both manual and computer-generated dose calculations;
- (4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;
- (5) Determining if a medical event, as defined in § 35.3045, has occurred; and
- (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Contrary to the above, from March 16, 2017, through March 24, 2021, for any administration requiring a written directive, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's existing written procedures and policies failed to address (b)(5), with regards to the determination of a medical event for unsealed radioiodine therapies, and for manual brachytherapy, failed to address (b)(2), (3), (5), and (6). While the licensee's routine practices appeared to capture the necessary actions, the licensee's written procedures and policies failed to capture the above-quoted information as required.

Upon determination that the existing procedures did not adequately address these minimum requirements, the licensee committed to re-writing the applicable policies/procedures to capture the necessary information within 30-days.

From: [Steven Matthes](#)
To: [VonEhr, Jason](#); [Jeff Fairbanks](#)
Cc: [Christen Turner](#); [Andrew Cupino MD](#); [W Lee Bowlby](#); [Wendi Thompson](#)
Subject: [External_Sender] RE: NRC Inspection Report - St. Peter's Hospital
Date: Monday, April 05, 2021 11:27:23 AM
Attachments: [image001.jpg](#)
[image003.jpg](#)
[Signed NRC SPHealth 2021.PDF](#)

Thanks again Jason.

All the best,
steve

Gold Standard is inevitable.
Wade Johnson

email signature



From: VonEhr, Jason [mailto:Jason.VonEhr@nrc.gov]
Sent: Monday, March 29, 2021 10:33 AM
To: Jeff Fairbanks <jfairbanks@radiationphysics.com>
Cc: Christen Turner <ChTurner@sphealth.org>; Andrew Cupino MD <ACupino@sphealth.org>; Steven Matthes <SMatthes@sphealth.org>; W Lee Bowlby <WBowlby@sphealth.org>
Subject: NRC Inspection Report - St. Peter's Hospital

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Jeff Et. Al.,

I'd like to thank you for your time today and during the NRC's remote inspection of St. Peter's Hospital's Helena, Montana, facilities. As I briefly discussed today, the NRC has determined that two SLIV violations of NRC regulatory requirements were identified. The attached NRC Inspection Report (NRC Form 591M) documents the results of the inspection. Please review the violations and the description of your corrective actions to confirm their accuracy, as they've been written based on my understanding of your actions.

If you concur with the violation and corrective actions as written: Mr. Matthes - please sign your name in the provided space, scan the document back to me, and keep your copy for your records. If you have questions or concerns about either or both the violation(s) and corrective action(s), please reach out to me and let us discuss it.

Regarding the signature: If you have a method to digitally sign a document, you may use this, or alternatively the 'old fashioned' way of printing, signing, and scanning the resultant document back. Please ensure that when returned, the document has *both pages*.

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Jason vonEhr
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