



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

December 14, 2017

EA-17-181

Mr. Mark Parkinson, Administrator
St. Luke's Regional Medical Center
190 E. Bannock
Boise, ID 83712

SUBJECT: NRC INSPECTION REPORT 030-32196/2017-001 AND NOTICE OF VIOLATION

Dear Mr. Parkinson:

This letter refers to the routine unannounced inspection conducted on August 28, August 31, and September 1, 2017, at your facilities in Twin Falls and Boise, Idaho. This inspection examined activities conducted under your license as they relate to public health and safety, the common defense and security, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel. The enclosed inspection report presents the results of this inspection. The inspector discussed the preliminary inspection findings with you and other personnel on September 1, 2017, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and other licensee personnel on December 5, 2017.

Based on the results of this inspection, apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. One or more apparent violations involving security requirements are discussed in the non-public Enclosure 2. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and other personnel on September 1, 2017.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for the apparent violations at this time. In addition, please be advised that the number and characterization of apparent violations described in Enclosure 2 may change as a result of further NRC review.

**Enclosure 2 contains Sensitive
Unclassified Non-Safeguards
Information. When separated from
Enclosure 2, this cover letter and
Enclosure 1 are decontrolled.**

M. Parkinson

2

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a predecisional enforcement conference (PEC) or (2) request alternative dispute resolution (ADR). If a PEC is held, the NRC may issue a meeting notice to announce the time and date of the conference; however, the PEC will be closed to public observation since Security-Related Information will be discussed. If you decide to participate in a PEC or pursue ADR, please contact Mr. Michael C. Hay, Chief, Materials Licensing and Inspection Branch, at 817-200-1455 within 10 days of the date of this letter to notify the NRC of your intended response. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. 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 Web site at <http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Cornell University Scheinman Institute on Conflict Resolution (Cornell) has agreed to facilitate the NRC's program as a neutral third party. Please contact Cornell at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Additionally, based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the enclosed Notice because they were identified by the NRC during the inspection. The violations involved: (1) the failure to assure operation of the electrical interlocks at a remote afterloader unit room entrance, and (2) the possession and use of byproduct material in permanent implant brachytherapy sealed sources with model numbers that were not authorized to be possessed and used under your NRC license.

M. Parkinson

3

You are required to respond to the Notice in Enclosure 1 and should follow the instructions specified in the enclosed Notice when preparing your response. As previously discussed, the guidance in NRC Information Notice 96-28, may be helpful in preparing your response. Information regarding the reason for the violations, 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 and Enclosure 1 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>.

However, the material in Enclosure 2 contains Security-Related Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosure will not be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's ADAMS. If Security-Related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

If you have any questions concerning this matter, please contact Mr. Michael C. Hay of my staff, at 817-200-1455.

Sincerely,

/RA by LLHowell Acting For/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

License No. 11-27312-01
Docket No. 030-32196

Enclosures:

1. Notice of Violation
2. NRC Inspection
Report 030-32196/2017-001

cc w/enclosures:
Mark Dietrich, Administrator
Idaho Dept. of Environmental Quality

NOTICE OF VIOLATION

St. Luke's Regional Medical Center
Boise, Idaho

Docket No. 030-32196
License No. 11-27312-01
EA-17-181

During an NRC inspection conducted on August 28, August 31, and September 1, 2017, at the licensee's facilities located in Twin Falls and Boise, Idaho, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.643(d) requires, in part, that to satisfy the requirements of 10 CFR 35.643(a), spot-checks for remote afterloader units must, at a minimum, assure operation of the electrical interlocks at each remote afterloader unit room entrance.

10 CFR 35.615(b) requires, in part, that a licensee shall equip each entrance to the treatment room with an electrical interlock system that will cause the source to be shielded when an entrance door is opened.

Contrary to the above, from May 28, 2015, to September 1, 2017, during spot-checks the licensee failed to assure operation of the electrical interlocks at each remote afterloader unit room entrance. Specifically, during periodic spot-checks of the licensee's remote afterloader unit located at its facility in Boise, Idaho, the licensee failed to assure that operation of the electrical interlocks at the remote afterloader unit room entrance will cause the source to be shielded when the entrance door to the afterloader unit room is opened.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

- B. License Condition 7.D. of NRC License 11-27312-01, Amendments No. 64 through 72, lists the physical form of byproduct material that is authorized to be possessed and used by the licensee for manual brachytherapy procedures permitted by 10 CFR 35.400. Under "physical form", License Condition 7.D. lists the specific manufacturer and model numbers of sealed sources authorized to be possessed and used by the licensee for procedures permitted by 10 CFR 35.400.

Contrary to the above, from January 26, 2015, to September 1, 2017, for manual brachytherapy procedures permitted by 10 CFR 35.400, the licensee possessed and used byproduct material in sealed sources with model numbers that were not authorized to be possessed and used under License Condition 7.D. of NRC License 11-27312-01, Amendments No. 64 through 72. Specifically, the licensee possessed and used Theragenics Corporation Model AgX100 sealed sources, in the form of 665 brachytherapy seeds, each containing an average of 0.36 millicuries of iodine-125, and the licensee was not authorized to possess and use Theragenics Corporation Model AgX100 sealed sources.

This is a Severity Level IV Violation (NRC Enforcement Policy, Section 6.3).

Enclosure 1

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~

Pursuant to the provisions of 10 CFR 2.201, St. Luke's Regional Medical Center 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 Director, Division of Nuclear Materials Safety, 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; EA-17-181" and should include, for each violation: (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, 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 14th day of December 2017

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4

NRC INSPECTION REPORT 030-32196/2017-001 - DATED DECEMBER 14, 2017

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ADAMS ACCESSION NUMBER – PUBLIC: LETTER AND Enclosure 1: ML17348B491

ADAMS ACCESSION NUMBER – NON-PUBLIC: LETTER W/Enclosure 1 and Enclosure 2: ML17338A082

Cover Letter (w Enc 1) X SUNSI Review by: JFK	ADAMS X Yes <input type="checkbox"/> No	X Publicly Available <input type="checkbox"/> Non-Publicly Available	X Non-Sensitive <input type="checkbox"/> Sensitive	Keyword: EA-17-181		
Cover Letter (w/Enc 1 and Enc 2) X SUNSI Review by: JFK	ADAMS X Yes <input type="checkbox"/> No	<input type="checkbox"/> Publicly Available X Non-Publicly Available	<input type="checkbox"/> Non-Sensitive X Sensitive	Keyword: MD A.3		
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