



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

August 11, 2016

Mr. James McKenna
Director, Medical Imaging and Radiation Oncology
Fairbanks Memorial Hospital
1650 Cowles Street
Fairbanks, AK 99701

SUBJECT: NRC INSPECTION REPORT 030-03509/2016-001 AND NOTICE OF VIOLATION

Dear Mr. McKenna:

This letter refers to the routine, unannounced inspection conducted on June 23, 2016, at your facility in Fairbanks, Alaska. 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. The preliminary inspection findings were discussed with Dr. Greg Johnson, Chief Executive Officer, you, and other members of your staff at the conclusion of the onsite portion of the inspection. After the onsite inspection, records that were not available during the onsite inspection were provided by your staff, and additional interviews were conducted telephonically with individuals that were not present during the onsite inspection. A final telephonic exit briefing was conducted with you and members of your staff on August 9, 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, which can be found at the NRC's Web site at 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 a failure to follow NRC regulations related to written directives for 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 violation 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 817-200-1191.

Sincerely,

/RA/

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

Docket: 030-03509
License: 50-13648-01

Enclosure:
Notice of Violation

cc w/Enclosure:
Clyde E. Pearce, Chief
Radiological Health Program
Section of Laboratories
State of Alaska/DH&SS
5455 Dr. Martin Luther King, Jr., Ave.
Anchorage, AK 99507-1270

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 Clyde E. Pearce, Chief
 Radiological Health Program
 State of Alaska/DH&SS
 5455 Dr. Martin Luther King, Jr., Ave.
 Anchorage, AK 99507-1270

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OFFICE	RIV:NMSB-A	RIV:C:NMSB-A			
NAME	JFKatanic	RLKellar			
SIGNATURE	<i>/RA/</i>	<i>/RA/</i>			
DATE	08/10/16	08/11/16			

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NOTICE OF VIOLATION

Fairbanks Memorial Hospital
Fairbanks, Alaska

Docket No. 030-03509
License No. 50-13648-01

During an NRC inspection conducted on June 23, 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 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, on April 8, 2014, the licensee failed to ensure that a written directive was dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material and failed to ensure that the before implantation written directive contain the treatment site and radionuclide. Specifically, on April 8, 2014, for an administration of a therapeutic dose of radiation from byproduct material from manual permanent implant brachytherapy, the written directive: (1) was not dated and signed by an authorized user before the administration; (2) before implantation, did not contain the treatment site and radionuclide.

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

Pursuant to the provisions of 10 CFR 2.201, Fairbanks Memorial 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, United States 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 11th August 2016