



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

July 13, 2016

John J. McCormick, M.D.
Radiation Safety Officer
Rehabilitation Medicine Associates, PC
3801 University Lake Drive, Suite 102
Anchorage, AK 99508

SUBJECT: NRC INSPECTION REPORT 030-38049/2016-001 AND NOTICE OF VIOLATION

Dear Dr. McCormick:

This letter refers to the routine, unannounced inspection conducted on June 21, 2016, at your facility in Anchorage, 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 you at the conclusion of the onsite portion of the inspection. A final telephonic exit briefing was conducted with you on July 5, 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 involved the failure to document the basis for authorizing the release of individuals after the administration of unsealed byproduct material. The violation is being cited in the enclosed Notice because it was identified by the NRC 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 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: 030-38049
License: 50-29349-01

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

J. McCormick

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Cc w/Enclosure:
Clyde E. Pearce, Chief
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5455 Dr. Martin Luther King, Jr., Ave
Anchorage, AK 99507-1270

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Cover Letter (w/ Enclosure) X SUNSI Review by: JEV		ADAMS X Yes <input type="checkbox"/> No	X Publicly Available <input type="checkbox"/> Non-Publicly Available	X Non-Sensitive <input type="checkbox"/> Sensitive	Keyword: N/A
OFFICE	RIV:NMSB-A	RIV:NMSB-A	RIV:C:NMSB-A		
NAME	JEvonEhr	JFKatanic	RLKellar		
SIGNATURE	/RA/	/RA/	/RA/		
DATE	07/07/2016	07/07/2016	07/13/16		

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NOTICE OF VIOLATION

Rehabilitation Medicine Associates, PC
Anchorage, Alaska

Docket No. 030-38049
License No. 50-29349-01

During an NRC inspection conducted on June 21, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 16 of NRC License 50-29349-01, Amendment No. 01, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures.

License application dated May 19, 2009, Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials," Section U.3.1, "Records of Release" describes the licensee's procedures and method for documenting the release of patients *other than* those who were released in accordance with Column 1 of Table U.1., Section U.3.1, describes that for these individuals, a record of the basis for release is required by 10 CFR 35.75(c) and should include the patient identifier, the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, the records should include the following: (1) For Immediate Release of a Patient Based on a Patient-Specific Calculation: The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The basis for selecting each of these values should be included in the record; or (2) For Immediate Release of a Patient Based on Measured Dose Rate: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

Contrary to the above, from March 6, 2013 to June 21, 2016, the licensee immediately released patients *other than* those who were released in accordance with Column 1 of Table U.1. and failed to record the basis for release of these individuals. Specifically, on January 19, 2015, June 16, 2015, and November 20, 2015, the licensee released patients that were administered between approximately 100 and 150 millicuries of unsealed iodine-131, and did not record the basis for the immediate release of the patients, based on either a patient-specific calculation or the measured dose rate.

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

Pursuant to the provisions of 10 CFR 2.201, Rehabilitation Medicine Associates, PC, 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" 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,

Enclosure

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 13th day of July 2016