



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

November 7, 2016

Dr. Alan Skolnick
Radiation Safety Officer
Alaska Heart Institute
3841 Piper Street, Suite T1-100
Anchorage, Alaska 99508

SUBJECT: NRC INSPECTION REPORT 030-34474/2016-001 AND NOTICE OF VIOLATION

Dear Dr. Skolnick:

This letter refers to the routine, unannounced inspection conducted on September 21, 2016, at your facilities in Anchorage and Palmer, 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 Cathy McVey, Clinical Services Manager, on October 17, 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 license conditions with regard to the eating, drinking, and storage of food or drink in areas where licensed radioactive material was used or stored.

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 by JLTompson Acting For/

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

Docket: 030-34474
License: 50-29111-01

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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Cover Letter (w/ Enclosure) 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: N/A
OFFICE	RIV:NMSB-A	RIV:C:NMSB-A			
NAME	JFKatanic	RLKellar			
SIGNATURE	/RA/	/RA by JLTompson Acting For/			
DATE	10/20/16	11/07/16			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Alaska Heart Institute, LLC
Anchorage, Alaska

Docket No. 030-34474
License No. 50-29111-01

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

License Condition 15 of NRC License 50-29111-01, Amendment No. 20, requires, in part, that the licensee conduct its program in accordance with license application dated July 21, 2012. License application dated July 21, 2012, Item 10.12, "Safe Use of Unsealed Licensed Materials," states "Do not eat, drink, smoke, or apply cosmetics in areas where radioactive material is stored/used. Do not store food, drink, or personal effects with radioactive material."

Contrary to the above, on September 21, 2016, the licensee failed to conduct its program in accordance with Item 10.12, "Safe Use of Unsealed Licensed Materials," in license application dated July 21, 2012. Specifically, two examples of the licensee's failure to follow the "Safe Use of Unsealed Licensed Material," were identified: (1) a licensee employee was observed with a container of coffee, walking through the hot lab, an area where unsealed licensed radioactive materials are used and stored, and (2) numerous food and drink items, including: opened packages of crackers, opened jars of honey and jelly, packages of coffee and tea, candies and cookies, a can of ham, and containers of coffee creamer were observed to be stored in the hot lab, an area where unsealed licensed radioactive materials are used and stored.

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

Pursuant to the provisions of 10 CFR 2.201, Alaska Heart Institute, LLC, 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.

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

Enclosure

(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 7th day of November 2016