



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 2, 2006

Docket No. 03036969

License No. 45-31062-01

Fareeha I. Khan, M.D.
Virginia Heart, Inc.
2826 Old Lee Highway, Suite 100
Fairfax, VA 22031

**SUBJECT: INSPECTION 03036969/2006001, VIRGINIA HEART, INC., FAIRFAX,
VIRGINIA SITE AND NOTICE OF VIOLATION**

Dear Dr. Khan:

On August 3, 2006, Steven Courtemanche of this office conducted a safety inspection at the above address of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In addition to the violations identified, the inspector noted that your technologist performed radiation surveys at the end of the day in locations where licensed material was used but did not identify several areas of radioactive contamination in the stress-testing area and in the imaging room. It is our understanding that these locations are accessible after normal working hours to non-radiation workers. In addition to the response required by the enclosed Notice, please indicate what actions you will take to ensure that unrestricted areas will be free of contamination when accessible to non-radiation workers or confirm that these areas will be restricted.

F. Khan
Virginia Heart, Inc.

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Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Virginia

F. Khan
Virginia Heart, Inc.

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NOTICE OF VIOLATION

Virginia Heart, Inc.
Fairfax, VA

Docket No. 03036969
License No. 45-31062-01

During an NRC inspection conducted on August 3, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive material, and the potential radiological hazards that could be present. Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

10 CFR 20.1201(a)(2)(ii) limits radiation exposure to the skin of the whole body or the extremities of occupationally exposed individuals to less than 50 rem shallow dose equivalent.

Contrary to the above, on August 3, 2006, the licensee did not make surveys that were necessary and reasonable to assure compliance with 10 CFR 20.1201(a)(2)(ii), which limits radiation exposure to the skin of the whole body or the extremities of occupationally exposed individuals to less than 50 rem shallow dose equivalent. Specifically, at the end of the work day on August 3, 2006, prior to leaving the licensee's facility, a technologist performed a survey of his person for radioactive contamination and failed to detect: (1) contamination measuring 5 milliRoentgen (mR) per hour covering approximately 10 square centimeters of skin on the index finger and middle finger of his left hand; and (2) contamination measuring 0.5 mR per hour covering an area of approximately 30 square centimeters of skin on the palm of his right hand. Radioactive contamination directly on the skin can result in significant exposures if not identified and removed in a short period of time. Additional areas of contamination were found on the technologist's clothing.

This is a Severity Level IV violation (Supplement IV).

- B. 10 CFR 35.63(a) requires that a licensee determine and record the activity of each dosage before medical use. 10 CFR 35.63(b) requires, in part, that for a unit dosage, this determination must be made by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State regulations.

Contrary to the above, between July 27 and August 3, 2006, the licensee did not determine and record the activity of each unit dosage before medical use by direct measurement or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent

Agreement State regulations. Specifically, the licensee simply recorded the administered activity as the activity determined by the preparer licensed under 10 CFR 32.72, without correcting for decay.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Virginia Heart, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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 for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, 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 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 2 day of September 2006