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

April 11, 2007

Docket No. 03035780 License No. 45-25064-02

Mark W. Clark, M.D., Director
Tidewater Heart Specialists, Inc.
2112-B Hartford Road
Hampton, VA 23666

SUBJECT: INSPECTION 03035780/2007001, TIDEWATER HEART SPECIALISTS, INC., HAMPTON, VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Dr. Clark:

On January 31, 2007, Thomas K. Thompson 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 your Radiation Safety Officer, Dr. Derrick E. Ridley, at the conclusion of the inspection. Additional information, provided during a telephone conversation between Dr. Ridley and Mr. Thompson on April 11, 2007, was also considered for this 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. In addition to the violations, the inspector determined that: (1) the technologist performed daily checks of dose calibrator constancy using a cobalt-57 source but did not know the decayed activity of the source and therefore could not assess the operability of the dose calibrator; and (2) the technologist performed ambient radiation surveys of the facility with a survey instrument that was not checked for operation. These deficiencies were not cited as violations because the regulations in Part 35 no longer require use of a dose calibrator when only unit patient dosages are purchased and administered without adjustment to patients and ambient radiation surveys are only required where byproduct materials requiring a written directive are used. These two deficiencies and Violation A reflect poor training and oversight of the technologist.

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.

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:
Derrick E. Ridley, M.D., Radiation Safety Officer
Commonwealth of Virginia

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

Enclosure:
Notice of Violation

cc:
Derrick E. Ridley, M.D., Radiation Safety Officer
Commonwealth of Virginia

Distribution:
D. J. Holody, RI

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SUNSI Review Complete: JDwyer
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NAME	JDwyer		Tthompson JPD1					
DATE	4/11/2007		4/11/2007					

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NOTICE OF VIOLATION

Tidewater Heart Specialists, Inc.
Hampton, VA

Docket No. 03035780
License No. 45-25064-02

During an NRC inspection conducted on January 31 - April 11, 2007, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1501 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 that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, 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.

Contrary to the above, prior to January 31, 2007, the licensee did not make surveys to assure compliance with 10 CFR 20.1906(b) which limits contamination levels on external surfaces of packages labeled with a Radioactive White I, Yellow II, or Yellow III label, and the packages were not exempt from the monitoring requirement. Specifically, the package surveys were performed by the licensee using an instrument for which neither the efficiency nor the operability was determined.

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

B. 10 CFR 35.14(b)(4) requires that a licensee notify the Commission no later than 30 days after the licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 10 CFR 35.100 or 35.200.

Contrary to the above, in 2006, the licensee added to the areas of byproduct material use identified in the application and, as of January 31, 2007, a period in excess of 30 days, the licensee had not notified the Commission. Specifically, in 2006 the licensee added a lock box to the exterior of the facility to receive byproduct material shipments after normal working hours.

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

Pursuant to the provisions of 10 CFR 2.201, Tidewater Heart Specialists, 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 11th day of April, 2007