

OCT 24 1994

Cardiovascular Associates, Ltd.  
ATTN: William L. Volkman  
Administrator  
2901 West Kinnickinnic River Parkway  
Milwaukee, WI 53215

Dear Mr. Volkman:

This refers to the routine safety inspection conducted by Robert Gattone of this office on August 29, 1994, with continuing NRC review through September 24, 1994, of activities authorized by NRC Byproduct Material License No. 48-26423-01, and to the discussion of our findings with you at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

Notwithstanding the guidance contained in 10 CFR Part 2, Appendix C, Section VII.B.1. of the NRC Enforcement Policy, we are not exercising discretion and are issuing Violation Nos. 3. and 4. of the enclosed Notice. Adequate corrective actions were not available at the time of the inspection.

In addition to the violations, we are concerned that the level of involvement in radiation safety activities by your Radiation Safety Officer (RSO) may not be adequate. Per 10 CFR 35.21, the licensee, through the Radiation Safety Officer (RSO), is responsible for ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Successful oversight enables licensees to: (1) self-identify problems/weaknesses; (2) implement prompt, effective corrective actions; and (3) monitor the effectiveness of the corrective actions taken to prevent recurrence. Effective oversight may necessitate, among other things, requiring the RSO to devote more time performing his/her duties, establishing a self audit system, and/or acquiring consulting services. Please address this concern by providing a description of the actions you have taken or plan to take to enhance your RSO's involvement and oversight of the radiation safety program.

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In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief  
Nuclear Materials Safety Branch

License No. 48-26423-01  
Docket No. 030-32821

Enclosure: Notice  
of Violation

bcc w/enclosure:  
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