

February 21, 2001

IA-01-004

James Halstead
Biomedical Scanning Services, Inc.
9445 Chavez Drive
St. Louis, MO 63126

SUBJECT: NOTICE OF VIOLATION
(INVESTIGATION REPORT NO. 3-2000-014)

Dear Mr. Halstead:

This refers to the Office of Investigations (OI) report number 3-2000-014, completed on December 15, 2000, to determine whether byproduct material was deliberately ordered to be delivered to an unauthorized location. On March 3, 2000, a review of licensed activities was conducted to evaluate whether receipt of byproduct material was in accordance with your license and NRC requirements. This review identified an apparent deliberate violation involving the delivery of byproduct material directly to a hospital. Based on this review, the OI investigation was performed. Our January 12, 2001 letter, discussed the apparent violations, our decision to hold a predecisional enforcement conference with you, and provided you a summary of the OI investigation. On January 25, 2001, a predecisional enforcement conference was conducted in the Region III office, Lisle, Illinois, with you to discuss the apparent violations, their significance, their root causes, and your corrective actions.

Based on the information developed during a January 26, 2000 inspection, the March 3, 2000 review, the investigation, and the additional information that you provided during the conference, the NRC has determined that deliberate violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and involved: (1) deliberately allowing byproduct materials to be delivered to Biomedical's mobile van without an authorized individual always present between December 23, 1997 and at least February 10, 2000; (2) deliberately ordering byproduct materials to be delivered directly to a client's address of use between October 1998 and February 10, 2000; and (3) providing incomplete or inaccurate information to NRC staff during a January 26, 2000 routine inspection, and a March 3, 2000 review of byproduct material receipt practices. Your deliberate actions placed Biomedical in violation of: (1) 10 CFR 35.29, "Administrative requirements that apply to the provision of mobile nuclear medicine service"; (2) 10 CFR 30.9, "Completeness and accuracy of information"; and (3) License Condition 14 of its License. Your deliberate actions also placed you in violation of 10 CFR 30.10, "Deliberate Misconduct." Given the deliberate nature of your actions, and since you are the president and radiation safety officer, these violations have been categorized in accordance with Supplement VII of the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, May 1, 2000, as a Severity Level II problem.

In determining the appropriate sanction to be issued in this case, the NRC considered issuing an Order prohibiting your involvement in NRC-licensed activities because of your actions. However, after consultation with the Director, Office of Enforcement, and after considering the circumstances of this case, including the facts that: (1) the actual safety significance was low; (2) the enforcement action against Biomedical Scanning Services have a direct impact on you since you are the owner and sole employee; and (3) you indicated during the conference that you understand the significance of your actions, I have decided to issue the enclosed Notice of Violation.

You should be aware that additional deliberate violations could result in more significant enforcement action.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Please feel free to contact Mr. Geoffrey Wright of my staff if you have any questions. Mr. Wright can be contacted at telephone numbers (630) 829-9500 or (800) 522-3025.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," 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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Sincerely,

/RA/ James L. Caldwell for

J. E. Dyer
Regional Administrator

Enclosure: Notice of Violation

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OE:IA (2)

State of Missouri

NOTICE OF VIOLATION

James Halstead

IA-01-004

During an NRC review of licensed activities on March 3, 2000, and an investigation completed on December 15, 2000, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, May 1, 2000, the violations are listed below:

1. 10 CFR 30.10(a)(1) prohibits an employee of a licensee from engaging in deliberate misconduct that causes a licensee to violate any regulation or term, condition, or limitation of its NRC license.

10 CFR 30.10(c)(1) states, in part, that for purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows would cause a licensee to be in violation of any rule or regulation.

10 CFR 35.29(d) requires that a mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

Contrary to the above, you engaged in deliberate misconduct that caused Biomedical Scanning Services to be in violation of 10 CFR 35.29(d), in that on numerous occasions from October 1998 to February 10, 2000, you ordered byproduct material to be delivered by a nuclear pharmacy directly to St. Genevieve Memorial Hospital, St. Genevieve, Missouri, a client's address of use serviced by Biomedical Scanning Services, Inc. (010102)

2. 10 CFR 30.10(a)(1) prohibits an employee of a licensee from engaging in deliberate misconduct that causes a licensee to violate any regulation or term, condition, or limitation of its NRC license.

10 CFR 30.10(c)(1) states, in part, that for purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows would cause a licensee to be in violation of any rule or regulation.

License Condition No. 14, dated December 23, 1997, states, in part, that the licensee conducts its program in accordance with the statements, representations, and procedures contained in a letter, dated September 29, 1997. Item A. of the September 29, 1997 letter, states, in part, that an authorized recipient will be present during all deliveries of byproduct material from the supplier.

Contrary to the above, you engaged in deliberate misconduct causing Biomedical Scanning Services to be in violation of Item A of the September 29, 1997 letter, in that on numerous occasions between December 23, 1997 and February 10, 2000, byproduct material was delivered to a mobile van and you did not ensure that an authorized recipient was present during the deliveries of byproduct material. (010202)

3. 10 CFR 30.10(a)(2) prohibits an employee of a licensee from deliberately submitting to the NRC information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

Contrary to the above, on January 26 and March 3, 2000, as the owner/radiation safety officer, you deliberately provided information to the NRC that was incomplete or inaccurate in some respect material to the NRC as follows:

- a. During the January 26, 2000 inspection, you provided incomplete information to an NRC inspector when questioned about receipt of byproduct material and failed to inform the inspector: that an authorized individual was not always present to receive material at the mobile van; and, that byproduct material was being ordered to be delivered directly to at St. Genevieve Memorial Hospital (St. Genevieve), a client's address of use. Further, you questioned the inspector about how Biomedical could arrange to receive unit doses at a client hospital and were advised by the inspector that a license amendment would be required.
- b. During the March 3, 2000 inspection, you provided inaccurate information to the NRC inspector when questioned as to whether you were previously informed that ordering byproduct material to be delivered directly to a client's address of use was a violation. You stated to the inspector that you were not advised by the NRC until the January 26, 2000 inspection, that ordering byproduct material to be delivered directly to St. Genevieve was a violation. However, during a June 7, 1999, telephone conversation, you were informed by an NRC license reviewer that ordering byproduct material to be delivered directly to a client's address of use was not allowed by the regulations.
- c. During the March 3, 2000 inspection, you provided inaccurate information to the NRC inspector when questioned about ordering byproduct material to be delivered directly to St. Genevieve. You stated that ordering byproduct material to be delivered directly to St. Genevieve had been discontinued on January 26, 2000. The statement was inaccurate in that ordering byproduct material to be delivered directly to St. Genevieve was not discontinued until February 10, 2000.

The above information was material to the NRC in that it prevented the NRC from properly assessing the control and security of byproduct materials. (010302)

This is a Severity Level II problem (Supplements VI and VII).

Pursuant to the provisions of 10 CFR 2.201, James Halstead is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region III, 801 Warrenville, Road, Lisle, IL 60532-4351 and marked "Open by Addressee Only" 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 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. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued. 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 R. W. Borchardt, Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room). 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 2.790(b) to support a request for withholding confidential commercial or financial information).

Dated this 21st day of February 2001.