JAN 7 1991

In Reply Refer To: License: 40-26908-01 Docket: 30-30273/90-02

W. A. Boade, M.D., Ltd. ATTN: W. A. Boade, M.D. 1100 South Euclid Sioux Falls, South Dakota 57117-5039

Gentlemen:

CC:

Thank you for your letter of December 19 1990, in response to our letter and attached Notice of Violation both dated November 30, 1990. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective action, during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Original Signed Ba A. B. BE A. Bill Beach, Director Division of Radiation Safety and Safeguards

TEOF

South Dakota Radiation Control Program Director

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WARDADEM

December 19, 1990

Mr. Bill Beach Dire. For Division of Radiation Safety & Safeguards United States Nuclear Regulatory Commission Region IV 611 Ryan Plaza urive Suite 1000 Arlington, TX 28001

Re: Notice of vicle is response. Docket #30-30273/90-02 License #10-26908

Pursuant to provision 10CFR 2.201 please allow chis to constitute written reply to violation severity level V violation.

Prior to October 26, 1990, inspection by your office it was our organizations policy to record swipe test results in CPM's contrary to your regulation stating they should be in DPM's. Following receipt of your notice of violation, we instituted a change in our format and all swipe tests of our mobile Tomo units are now recorded in DPM's per 100 cm. squared per regulatory requirements.

It is my hope that through this action the forsighted violation has been corrected.

Roder M. Rae Radiation Safety Officer W.A. Boade M.D., Ltd.

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License: 40-26908-01 Docket: 30-30273/90-02

W. A. Boade, M.D., Ltd. ATTN: W. A. Boade, M.D. 1100 South Euclid Sioux Falls, South Dakota 57117-5039

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner of this office on October 22-26, 1990, of the activities authorized by NRC Byproduct Material License No. 40-26908-01, and to the discussion of our findings held by the inspector with the radiation safety officer (RSO) at the conclusion of the inspection. This letter also acknowledges receipt of your letter dated September 27, 1990, in response to our letter and attached Notice of Violation both dated September 14, 1990, in regard to our June 20, 1990, inspection at your facility in Mankato, Minnesota.

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

During this inspection, certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter.

The inspector also reviewed the actions you had taken with respect to two violations observed during our previous inspection conducted on June 20, 1990, at the Mankato, Minnesota, facility. She verified that corrective actions had been taken regarding the failure to conduct dose calibrator constancy checks at each address of use. Although she noted that corrective measures had not been fully implemented at the time of the inspection, she observed that the required check sources had been obtained and, as verified by the RSO, that this requirement should be met within the timeframe indicated in your response. Since corrective actions had not been fully implemented, this item is considered open and will be reviewed during a future inspection. The second violation, involving a discrepancy in the Mankato facility address listed on the license, had been corrected by your request for license amendment which was subsequently issued by NRC on October 30, 1990.

The audits conducted by your consulting physicist had been effective in identifying four violations of NRC requirements. These violations involved

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W. A. Boade, M.D., Ltd.

the failure to: (1) maintain a record of molybdenum-99 content for each technetium-99m eluate which included notation of the ratio of the measurement expressed in m.crocuries of molybdenum-99 per millicurie of technetium as required under 10 CFR 35.204(c); (2) record the background dose rate for surveys conducted in association with disposal of material by decay-in-storage as required under 10 CFR 35.92(b); (3) conduct dose calibrator linearity tests over a range of activity as low as 10 microcuries as required under 10 CFR 35.50(b)(3); and (4) measure the ambient radiation dose rates quarterly in areas where sealed sources had been stored as required under 10 CFR 35.59(h). A fifth violation was identified by the inspector, involving the failure to include radiopharmaceutical expiration dates in patient dosage records as required under 10 CFR 35.53(c)(1).

These items have not been cited in the inclosed Notice, inasmuch as the inspector noted that the violations have not peen promptly corrected, the corrective actions had been properly documented, appeared to be adequate to prevent recurrence of these violations. Sinc these violations would normally be categorized as Severity Level IV and 2 violations, in accordance with Sections V.A. and V.G.1 of the NRC's Enforcement Policy, a Notice of Violation will not be issued for these specific violations. Your corrective actions will be reviewed during future inspections to ensure that they remain effective.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, 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 is 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.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,

Original Signed By: A. B. BEACH

A. Bill Beach, Director Division of Radiation Safety and Safeguards

Enclosure: Appendix ~ Notice of Violation

CC:

South Dakota Radiation Control Program Director

(A)

W. A. Boade, M.D., Ltd.

bcc: DMB - Original (IE-07) RDMartin ABBeach LAYandell MRodriguez, OC/LFDCB (4503) *WLFisher *CLCain *LLKasner *NMSIS *MIS System *RIV Files (2) *RSTS Operator *REHall, URFO

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APPENDIX

NOTICE OF VIOLATION

W. A. Boade, M.D., Ltd. Sioux Falls, South Dakota

Docket No. 30-30273/90-02 License No. 40-26908-01

During an NRC inspection conducted on October 22-26, 1990, a violation of NRC regularements was identified. In accordance with the "General Statement of Pulicy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violation is listed below:

License Condition 15 specifies, in part, that NRC License No. 40-26908-01 is based on the statements and representations in the application dated July 31, 1989.

Item 9.1 of the application specifies, in part, that the procedures described in Appendix N of Regulatory Guide 10.8, Revision 2, (RG 10.8) will be followed for radiation surveys of patient injection areas within the licensee's mobile scanning unit.

Appendix N of RG 10.8 specifies, in part, that areas where radiopharmaceuticals are prepared and __ministered will be surveyed weekly for removable contamination and that records of such surveys will be maintained including the measured contamination levels in disintegrations per minute (dpm) per 100 square centimeters.

Contrary to the above, as of October 26, 1990, the licensee had failed to maintain records of removable contamination surveys in units of dpm per 100 square centimeters for those surveys conducted in the licensee's mobile scanning unit, but had instead recorded the survey results in units of counts per minute per 100 square centimeters.

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

Pursuant to the provisions of 10 CFR 2.201, W. A. Boade, M.D., Ltd., is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice of Violation (Notice), a written statment or explanation in reply, including 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. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas this 30 day of Nov. 1990

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