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:

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 actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Original Signed By
A. B. BEACH

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

cc:
South Dakota Radiation Control Program Director

bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (MS 4503)
CLCain
WLFisher
LLKasner
NMSIS
MIS System
RIV Files (2)
RSTS Operator

RIV:NMSIS	C:NMSIS	D:DRSS
LLKasner:nh	CLCain	ABBeach
1/3/90	1/3/91	1/7/91

1/1

9101100185 910107
REG4 LIC30
40-26908-01 PDR

IE07

W.A. BOADE M.D., LTD.

Diagnostic Medical Imaging

December 19, 1990

Mr. Bill Beach
Director Division of Radiation Safety & Safeguards
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, TX 76001

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

Pursuant to provision 10CFR 2.201 please allow this 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.

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

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1100 South Euclid Avenue • Sioux Falls, South Dakota 57117 • (605) 335-1455

NOV 30 1990

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

RIV:NMSIS	C:NMSIS	D:DRSS
LLKasner	CLCain	RABeach
11/23/90	11/26/90	11/28/90

IE-07

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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 microcuries 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 enclosed Notice, inasmuch as the inspector noted that the violations have been promptly corrected, the corrective actions had been properly documented, and appeared to be adequate to prevent recurrence of these violations. Since these violations would normally be categorized as Severity Level IV and V 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

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

*W/766

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 requirements was identified. In accordance with the "General Statement of Policy 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 administered 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

NRC FORM 766 (11-81) IE MC 0535

U.S. NUCLEAR REGULATORY COMMISSION

INSPECTOR'S REPORT

Office of Inspection and Enforcement

PRINCIPAL INSPECTOR (Name, last, first, and middle initial): Kasner, Linda L.

REVIEWER: C. Cain

INSPECTORS

LICENSEE VENDOR	TRANSACTION TYPE	DOCKET NO (8 digits)	REPORT NO	SEQ	NEXT INSPEC DATE MO	YR
W.A. Boade, MD., LTD	X I - INSERT; M - MODIFY; D - DELETE; R - REPLACE	03030273	9002	A	10	92

PERIOD OF INVESTIGATION/INSPECTION FROM (MO DAY YR)	TO (MO DAY YR)	INSPECTION PERFORMED BY	OTHER	ORGANIZATION CODE: REGION	DIVISION	BRANCH
10 23 90	10 26 90	X 1 - REGIONAL OFFICE STAFF; 2 - RESIDENT INSPECTOR; 3 - PERFORMANCE APPRAISAL TEAM		4	3	4

REGIONAL ACTION (Check one box only): 1 - NRC FORM 591; X 2 - REGIONAL OFFICE LETTER

TYPE OF ACTIVITY CONDUCTED (Check one box only): X 02 - SAFETY (fee); 03 - INCIDENT; 04 - ENFORCEMENT; 05 - MGMT AUDIT; 06 - MGMT VISIT; 07 - SPECIAL (fee); 08 - VENDOR; 09 - MAT ACCT; 10 - PLANT SEC; 11 - INVENT VER; 12 - SHIPMENT/EXPORT; 13 - IMPORT; 14 - INQUIRY (no fee); 15 - INVESTIGATION

INSPECTION INVESTIGATION FINDINGS (Check one box only): X 1 - CLEAR; 2 - VIOLATION; 3 - DEVIATION; 4 - VIOLATION & DEVIATION

TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS: A: 0

ENFORCEMENT CONFERENCE HELD: 1 - YES

REPORT CONTAIN 2.790 INFORMATION: 1 - YES

LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG. LETTER ISSUED: 11 5 90; REPORT SENT TO HQ FOR ACTION:

MODULE INFORMATION

TYPE	NUMBER	MODULE NUMBER INSP	SEQ	DIRECT INSPEC. EFFORT (STAFF HOURS)	PERCENTAGE COMPLETED TO DATE	STATUS
8	1	53070 3 (management meetings)	A	001	---	-
8	1	58710 0 (licensed materials programs)	A	006	100	C
8	1	58382 2 (radiation protection)	A	005	100	C
8	1	58674 0 (transportation)	A	003	100	C
8	1	~~58425 0~~ (~~Inspection of Waste Generator Requirements~~)	A	0	100	C
8	1	~~53080 0~~ (~~initial inspection~~)	A	0	100	C
8	1	59270 2 (followup on violations)	A	001	---	-

● CIRCLE SEQUENCE IF VIOLATION OR DEVIATION

Mark through module numbers not reviewed. Fill in leading Ø's for hours.

NRC FORM 766 A

INSPECTOR'S REPORT
(Continuation)
Office of Inspection and Enforcement

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO.	SEQ.	MODULE NUMBER
03030273	9002	A	587100 SuppVI

VIOLATION OR DEVIATION

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