

DCD/DCB

LaserMike Inc. (Formerly TECHMET COMPANY)

The LEADER in
Non-Contact Gauging

A BUNZL Instrumentation Company

License File
34-25899-026

April 4, 1990

Charles E. Norelius, Chief
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Regarding: Your letter and Notice of Violation (NOV) dated
March 6, 1990

Dear Mr. Norelius:

We have received the abovementioned letter and Notice of Violation. It is evident from the nature of our violations that LaserMike is an inexperienced handler of radioactive materials. Let me assure you that our violations stem from ignorance of required procedures, and not from willful disregard of NRC regulations.

LaserMike management has carefully considered the N.O.V. issues and examined our operation to ascertain how we might most effectively:

- A. Correct existing oversights
- B. Establish procedures and control systems to ensure that violations will not be repeated
- C. Provide time frames for implementation of our plans.

The accompanying exhibits detail our responses to each violation and are incorporated by reference to this letter.

Hopefully, you and your staff will agree with us that our plans are broadly focused, effective, and have a high potential for long term effectivity. I say "potential" because any such plans or systems require management commitment and monitorization to maintain effectiveness. I ensure you that our management is committed to correcting the previous oversights and maintaining an organization which is compliant with NRC requirements.

9006270329 900404
REG3 LIC30
34-25899-26 PDC

IE07

APR 6 1990

Charles E. Norelius, Chief

April 4, 1990

An integral control feature of our proposed system is a "Probe Checklist" (see copy enclosed). This checklist will summarize all compliance issues (of which we are aware). I am requiring that no probe leave our premises until the checklist is completed (by our test and shipping departments), signed by our Radiation Safety Officer and by LaserMike's President. This monitorization and documentation requirement should ensure compliance with known regulations.

As an additional note, we conducted two training classes on March 9, 1990 wherein 21 LaserMike employees were trained on the NDC radioactive probe. The training was performed by Mr. Dan Fishman, President of NDC systems. All 21 people have since been issued certificates of Radiation Safety Training.

We wish to express our appreciation for the professionalism and courtesies extended to LaserMike by you and your staff. In particular, we thank Mr. Lambert for his patience and understanding of our situation. I look forward to personally meeting with you to express LaserMike's sincere desire to comply with NRC requirements.

Sincerely,

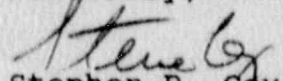

Stephen R. Cox
President

EXHIBIT 1

**Response to Notice of Violations
LaserMike, Inc.
April 4, 1990**

Violation Number -- 1

Type of Violation

Licensee Installed a device on July 7, 1989 and failed to conduct a radiation survey in the area to assure that the levels of radiation do not exceed those specified in License Condition No. 12.

Corrective Steps Taken

Mr. James Baker (LaserMike Service Mgr.), who has completed radiation safety training, visited the installation and performed the required survey. The installation was in compliance with License Condition No. 12. Copy of Mr. Baker's documentation is included as exhibit 1(a).

Steps Taken to Avoid Future Violations

1. LaserMike will require that installation arrangements be made with probe recipients prior to shipment.
2. Our shipping box will have a notice which requests the recipient not to open the box and hold until installer arrives.
3. We will require survey results to be physically attached to the checklist before the file is closed.

These will be conditions on the Probe Shipment Checklist. See example, exhibit 1(b).

Date of Full Compliance

March 6, 1990

EXHIBIT 1(a)

3-6-90

BAXTER

ID OD WALL 182 SYST.

182-11s SU 9-624

NOC PROBE MODEL 102 SU 2018

SOURCE AM 241

STRENGTH 5.55 GBg

DATE 06/89

SITE AREA READINGS

BACK GROUND $< .02$ m R/HR

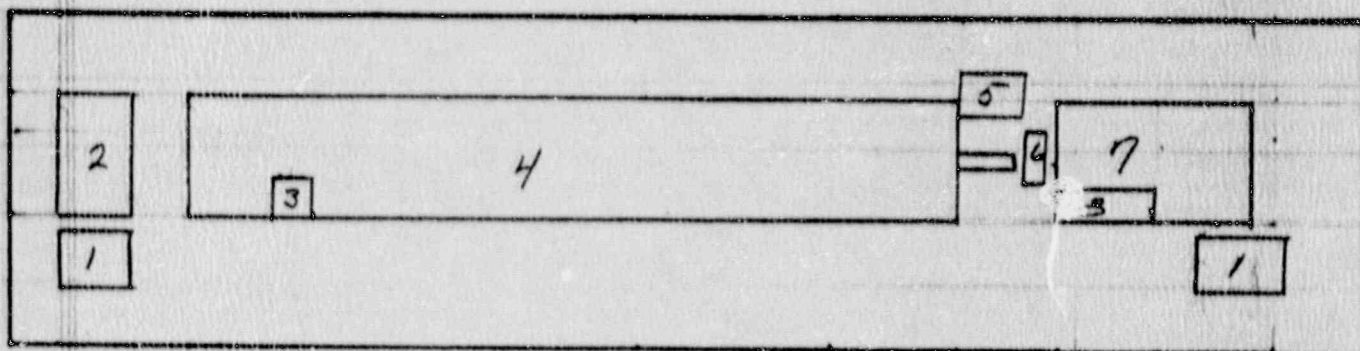
PROBE 2' RADIUS

SHUTTER CLOSED $< .02$ m R/HR

SHUTTER OPEN 2' RADIUS



BAXTER HEALTHCARE
RT 120 + WILSON RD
ROUND LAKE ILL. 60073



ROOM APPROX 70' LONG 17' WIDE 11' HIGH

- (1). OPERATOR WORK AREA
- (2). CUTTER, PULLER CONTROL PANEL
- (3). LASERMIKE NDC EQUIPMENT
- (4). CURING OVEN
- (5). CURING OVEN CONTROL PANEL
- (6). LASER SCAVER NDC PROBE
- (7). EXTRUDER
- (8). EXTRUDER CONTROL PANEL

NDC PROBE CHECK LIST

CUSTOMER ADDRESS _____ **P.O. #** _____

	Comments	Initials	Date
1. Probe Model Number	_____	_____	_____
2. Probe Serial Number	_____	_____	_____
3. Probe Labeled Correctly	_____	_____	_____

SHIPPING

4. Packed in approved box	_____	_____	_____
5. DOT 7A Labels, 2 sides of box	_____	_____	_____
6. Radioactive white I labels, 2 sides of box	_____	_____	_____
7. Radioactive white I labels filled out	_____	_____	_____
8. All carton seams taped	_____	_____	_____
9. To be opened by LaserMike Inc. personnel only label on box	_____	_____	_____
10. Carton survey performed	_____	_____	_____
11. Radiation level	_____	_____	_____
12. Declaration of dangerous goods okay	_____	_____	_____
13. Radioactive Device Notice	_____	_____	_____

SHIPMENT APPROVAL

Approved by RSO	_____	_____	_____
Approved by President	_____	_____	_____
Transfer notice sent to NRC, Wash., D.C. (Copy attached)	_____	_____	_____
Transfer notice sent to NRC or state (Copy attached)	_____	_____	_____

INSTALLATION

Installed by: _____	_____	_____	_____
Copy of installation report and survey attached	_____	_____	_____

AFTER INSTALLATION

Leak test results received; copy attached	_____	_____	_____
---	-------	-------	-------

COMPLETION OF TASKS APPROVAL

Approved by RSO	_____	_____	_____
Approved by President	_____	_____	_____

EXHIBIT 2

Response to Notice of Violations
LaserMike, Inc.
April 4, 1990

Violation Number -- 2

Type of Violation

Licensee failed to conduct a leak test of a device installed on July 7, 1989. A leak test is required by License Condition No. 15.

Corrective Steps Taken

LaserMike's Mr. James Baker (LaserMike Service Mgr.), who has completed radiation safety training, visited the installation and performed the leak test. The wipe test kit was sent to NDC systems for measurement. The results were returned to us on March 29, 1990 and the results were 4.0 Bq (see attached documentation, exhibit 2(a)).

Steps Taken to Avoid Future Violations

1. LaserMike will require that installation arrangements be made with probe recipients prior to shipment.
2. Our shipping box will have a notice which requests the recipient not to open the box and hold until installer arrives.
3. We will require leak testing to be performed at the time of installation. Upon the receipt of the results from NDC, the Radiation Safety Officer will evaluate and determine compliance. The certificate to be physically attached to the checklist before the file is closed.

These will be conditions on the Probe Shipping Checklist.

Date of Full Compliance

March 27, 1990



EXHIBIT 2(a)

730 EAST CYPRESS AVENUE
MONROVIA, CALIFORNIA 91016
(818) 358-1871, TWX 910-585-3480
EASYLINK 910-333-6254
FAX (818) 303-5770

COPY

INSTALLATION

LEAK TEST CERTIFICATE

Owner: BAXTER HEALTHCARE CORP.

Address: Round Lake, IL

Model/Serial Number: 102 S/N 2018

Source Number _____ 9473 LV _____

Manufacturer _____ Amersham _____

Isotope _____ Am-241 _____

Strength _____ 5.55 GBq _____

Model Number _____ AMCP1 _____

Date of Test _____ 03/27/90 _____

Results* _____ < 4.0 Bq _____

Dated:

Approved By:

_____ 03/27/90 _____


Daniel Fishman, President

* < 18 becquerels indicates non-leaking source.

EXHIBIT 3

Response to Notice of Violations
LaserMike, Inc.
April 4, 1990

Violation Number -- 3

Type of Violation

Each device distributed shall bear a durable, clearly visible and legible label containing information receipt, possession, use, and transfer; abandonment and disposal; operation, installation, dismantling, relocation, maintenance, repair and testing; leak testing; and loss, theft, or transfer.

Corrective Steps Taken

We have created self adhesive labels which contain the required information. See example below.

Mr. James Baker (LaserMike Service Mgr.), who has completed radiation safety training, visited the installation and attached the label to the probe in question.

Steps Taken to Avoid Future Violations

LaserMike's test department will attach the label to each probe. Our "Probe Checklist" will have this procedure as a "check item" which will be challenged by the Safety Radiation Officer upon his review. This monitorization and documentation requirement should ensure compliance with Licensee Condition Number 16.

Date of Full Compliance

March 6, 1990

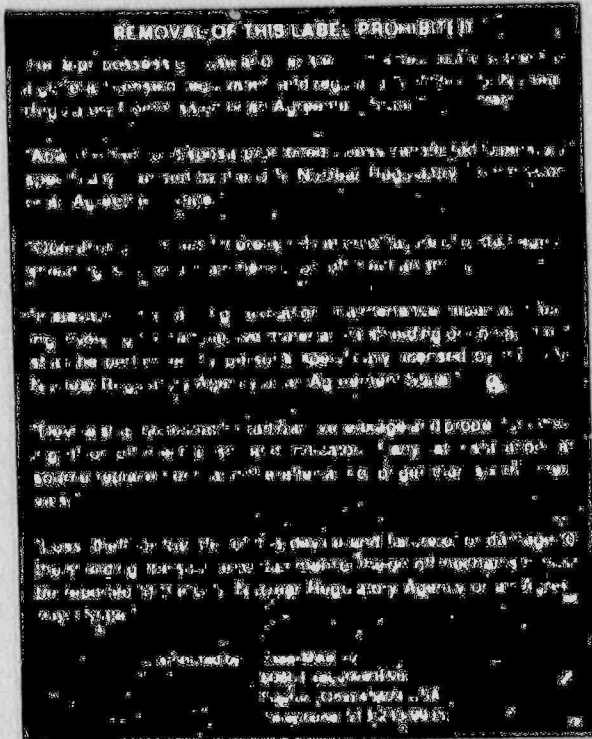


EXHIBIT 4

Response to Notice of Violations
LaserMike, Inc.
April 4, 1990

Violation Number -- 4(a)

Type of Violation

Licensee is to have their portable survey instrument calibrated annually.

Corrective Steps Taken

Our survey meter was sent to Radiation Service Organization in Laurel Maryland where National Institute of Standards Traceable Calibration was performed. A certificate of calibration dated February 8, 1990 was issued for the instrument (see copy attached as exhibit 4(a)(1).

Steps Taken to Avoid Future Violations

This instrument will be due for the recalibration on or before February 8, 1991. To prevent future violations, the RSO will maintain a tickler file to assure timely follow up. An additional and identical survey meter has been purchased to provide continuity and back up while one survey meter is absent due to for calibration or repair.

Date of Full Compliance

February 8, 1990

RSO, Inc.
 P.O. Box 1526
 Laurel, MD 20725
 (301) 953-2482

EXHIBIT 4(a)(1)

RSO ORDER # 2932
 P.O. # 21257

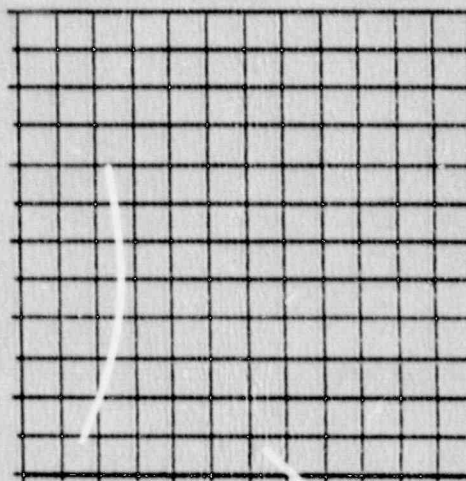
CERTIFICATE OF CALIBRATION

ISSUED TO Customer: LaserMike Inc. Address: 6060 Executive Blvd. City: Dayton State: OH Zip: 45424 Contact: Radiation Safety Phone: (513) 233-9935	INSTRUMENT Make: S. E. International Type: G-M Survey Meter Model: Monitor 4 Serial #: 20189
---	---

DETECTORS						
	Make	Type	Model	Serial Number	Voltage (V)	Radionuclide Efficiency
1.		Int. G-M			600	
2.						
3.						
4.						

RSO, Inc. certifies that on 2/8/90 the above described instrument was calibrated in a known radiation field using a ¹³⁷Cs (662 keV) beam calibrator (J.L. Shepard Model 28-6A, S/N 10056). The results are tabulated below. Calibration is traceable to the National Institute of Standards and Technology.

Scale or Range	Calculated (mR/h)	Observed (mR/h)	C.F.
x 1	0.100	0.100 *	1.00
	0.400	0.380 *	1.05
x 10	1.000	1.000	1.00
	4.000	3.800	1.05
x 100	10.000	10.000	1.00
	40.000	37.000	1.08



CALIBRATION GEOMETRY
 ORIENTATION TO RADIATION BEAM
 FRONT BACK PARALLEL PERPENDICULAR X

PROBE WINDOW
 OPEN X CLOSED FIXED

INSTRUMENT CHECKS

CHECK SOURCE: NA :

BATTERY CHECK: BATT

ENVIRONMENTAL CONDITIONS

Temperature: 25 °C

Pressure: 760 mmHg

Humidity: 50 %

Average correction factor: 1.03

COMMENTS

* Electronically pulsed.

This instrument should be returned for recalibration no later than 8/9/90

Calibrated By: Joshua K. Monk Reviewed By: 605 Date: 2/8/90
 Joshua K. Monk Maryland License MD-33-021-01

EXHIBIT 4(b)

**Response to Notice of Violations
LaserMike, Inc.
April 4, 1990**

Violation Number -- 4(b)

Type of Violation

Licensee did not have a Radiation Safety Officer between June 30, 1989 and August 8, 1989.

Corrective Steps Taken

The R.S.O. to be, initiated a request to amend our current license to change Radiation Safety Officer on July 20, 1989. The intervening 20 days were spent finding out what was involved in making these amendments and proceeding with the change. Compliance was achieved on August 8, 1989.

Steps Taken to Avoid Future Violations

This type of problem will not occur again as management now has an awareness of this issue. Our "Probe Checklist" requires Safety Radiation Officer signature prior to shipment. Absent the RSO, there will be no shipment. This monitorization and documentation requirement should ensure compliance.

Date of Full Compliance

August 8, 1989.

EXHIBIT 4(c)

Response to Notice of Violations
LaserMike, Inc.
April 4, 1990

Violation Number -- 4(c)

Type of Violation

Licensee failed to ship a device containing radioactive material in an authorized Type A package.

Corrective Steps Taken

LaserMike has obtained a supply of authorized "Type A" packaging as used by NDC systems to meet our short term needs.

Steps Taken to Avoid Future Violations

We have on order a new tri-wall carton which should easily meet these requirements and expect to receive it and have our testing completed by April 30, 1990. We will continue to use "Type A" materials supplied by NDC until we receive qualifying packaging from our vendor.

Date of Full Compliance

March 30, 1990

EXHIBIT 4(d)

**Response to Notice of Violations
LaserMike, Inc.
April 4, 1990**

Violation Number -- 4(d)

Type of Violation

LaserMike failed to evaluate the package shipped July 7, 1989 for contamination levels.

Corrective Steps Taken

No corrective action was possible for the material shipped on July 7, 1989.

Steps Taken to Avoid Future Violations

LaserMike's test department will be responsible to ensure by test that the external radiation and contamination levels are within allowable limits of 2.2 dpm/cm(squared).

Our "Probe Checklist" will have this procedure as a "check item" which will be challenged by the Safety Radiation Officer upon his review. This monitorization and documentation requirement should ensure compliance with DOT 49.CFR 173.475(i).

Date of Full Compliance

March 30, 1990

EXHIBIT 5

**Response to Notice of Violations
LaserMike, Inc.
April 4, 1990**

Violation Number -- 5

Type of Violation

Licensee failed to notify the Materials Licensing Branch, Division of Fuel Cycle and Material Safety of transfer of the device on July 7, 1989.

Corrective Steps Taken

Notification was performed on February 2, 1990. See copy of letter attached.

Steps Taken to Avoid Future Violations

LaserMike's has a procedure to complete the required notification prior to shipment of the radioactive material. Our "Probe Checklist" will have this procedure as a "check item" which will be challenged by the Safety Radiation Officer upon his review. This monitorization and documentation requirement should ensure compliance with Licensee Condition Number 17.

Date of Full Compliance

February 2, 1990