

Biomeasure

May 21, 1987

Mr. John D. Kinneman
Chief, Nuclear Materials
Safety Section A
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
Material Licensing Section B
631 Park Avenue
King of Prussia, PA 19406

License No.: 20-20539-01
Docket No.: 030-19392
Subject: Inspection No.: 030-19393/86-01

Dear Sir:

This letter is a reply to your letter dated May 15, 1987.

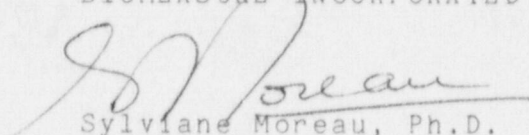
We apologize for our misunderstanding of item A-2. Please find enclosed Table I showing calculations of the concentrations of Carbone-14 and Tritium, released in the septic tank every year from 1983 to 1986. These concentrations are below the reference levels specified in 10 CFR Part 20, Appendix B, Table II, Column 2.

In reference to item B we would like to point out that liquid scintillation vials containing small amounts of Iodine-125 were removed by an NRC licensed transporter and not by a firm disposing of organic solvents.

We hope our response to the Notice of Violation is now complete.

Sincerely,

BIOMEASURE INCORPORATED


Sylviane Moreau, Ph.D.
RSO, Director of Operations

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20-20539-01 PDR

ANNUAL CONCENTRATIONS OF RADIOACTIVE MATERIAL RELEASED IN THE SEPTIC SYSTEM

<u>Year</u>	<u>Total Radioactivity Released (mCi)</u>		<u>Total Volume of Water Used</u>		<u>uCi/ml</u>	
	<u>¹⁴C</u>	<u>³H</u>	<u>cu ft</u>	<u>ml</u>	<u>¹⁴C</u>	<u>³H</u>
1983	0.028	0.66	101,030	$2.9 \cdot 10^9$	$9.66 \cdot 10^{-9}$	$2.28 \cdot 10^{-7}$
1984	0.011	21.21	138,700	$4.0 \cdot 10^9$	$2.75 \cdot 10^{-9}$	$5.30 \cdot 10^{-6}$
1985	14.41	223	119,040	$3.4 \cdot 10^9$	$4.24 \cdot 10^{-9}$	$6.56 \cdot 10^{-5}$
1986	0.227	1.59	101,980	$2.9 \cdot 10^9$	$7.83 \cdot 10^{-8}$	$5.45 \cdot 10^{-7}$

TABLE I

* 1 cu ft = 7.54 Gal. = 28.65L = $2.86 \cdot 10^4$ ml (1 Gal = 3.8L)

22 DEC 1986

Docket No. 030-19392

License No. 20-20539-01

Biomeasure, Inc.
ATTN: Dr. Sylviane Moreau
Operating Manager
11-15 E Avenue
Hopkington, Massachusetts 01748

Gentlemen:

Subject: Inspection No. 030-19393/86-01

This refers to the routine safety inspection conducted by John T. Jensen of this office on November 6, 1986 of activities authorized by NRC License No. 20-20539-01 and to the discussions of our findings held by Mr. Jensen 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 the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Our inspector also verified the steps you had taken to correct the Violations brought to your attention in a letter dated October 28, 1986. We have no further question regarding your action at this time.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These violations have been categorized by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses 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.

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12/04/86

RETURN ORIGINAL TO
REGION I

IE:07
1/1

22 DEC 1986

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosure: Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

bcc:
Region I Docket Room (w/concurrences)
Management Assistant, DRMA
J. Jensen, RI

RI:DRSS
Jensen/mm/emw

12/15/86

RI:DRSS
Kinneman

12/16/86

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12/04/86

APPENDIX A

NOTICE OF VIOLATION

Biomeasure, Inc.
Hopkington, Massachusetts 01748

Docket No. 030-19392
License No. 20-20539-01

As a result of the inspection conducted on November 6, 1986, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of November 6, 1986, evaluations were not made to assure compliance with 10 CFR 20.106, which limits radioactivity in effluents released to unrestricted areas.

1. Specifically, surveys were not performed to determine the concentrations of hydrogen-3 in the effluent discharged from a fume hood where seven curies of hydrogen-3 were processed at various times from August, 1985 through November, 1985.
2. Specifically, evaluations were not made of millicurie quantities of hydrogen-3 and carbon-14 in aqueous solutions released to the licensee's septic system from September 1, 1983 through June 1986.

These are Severity Level IV violations. (Supplement IV)

- B. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures.

Contrary to the above, as of February 26, 1986, iodine-125 was disposed of to the normal trash, a method not authorized by 10 CFR 20.301. Specifically, the licensee held a few hundred vials for decay for approximately one year and then assayed one vial that represented the maximum activity of any of the vials and determined that the activity in the vial was approximately 400 disintegrations per minute net activity and then disposed all of the vials to the normal trash.

This is a Severity Level IV violation. (Supplement IV)

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- C. 10 CFR 30.41(c) requires that, prior to transferring licensed material, each licensee verify that the transferee's licensee authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies the requirements for verifying authorization.

Contrary to the above, on December 1, 1984, approximately 175 microcuries of carbon-14 were transferred without utilizing one of the verification procedures.

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

- D. Conditions 6.D and 7.D of License No. 20-20539-01 limit the chemical form of iodine-125 that may be possessed to iodine-125 bound to a nonvolatile agent.

Contrary to the above, as of November 6, 1986, the licensee possessed approximately 5 millicuries of iodine-125 in the form of aqueous sodium iodine, which is a form not bound to a nonvolatile agent.

This is a Severity Level IV violation.

- E. Conditions 6.A and 8.A of License no. 20-20539-01 limit the amount of hydrogen-3 that may be possessed at any one time to a total of 10 curies.

Contrary to the above, from August, 1985 until February 26, 1986, the licensee possessed approximately 12.5 curies of hydrogen-3.

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

Pursuant to the provisions of 10 CFR 2.201, Biomeasure, Inc. is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

- CONVERSION FROM MILLICURIES TO MICROCURIES

	¹⁴ C	³ H
1983	9.6×10^{-9}	2.3×10^{-7}
1984	2.75×10^{-9}	5.3×10^{-6}
1985*	4.2×10^{-6} *	6.5×10^{-5}
1986	7.8×10^{-8}	5.5×10^{-7}

* THIS IS THE ONLY YEAR IN WHICH BIOMEASURE
DID NOT CORRECTLY CALCULATE THE CONCENTRATION

John T. Jensen
9/7/87