

DCD

October 17, 1996

Chun B. Lim, Ph.D., President  
Trionix Research Laboratory  
8037 Bavaria Road  
Twinsburg, OH 44087

SUBJECT: NOTICE OF VIOLATION DATED AUGUST 28, 1996

Dear Dr. Lim:

This acknowledges receipt of your letter dated September 26, 1996, in response to our letter dated August 28, 1996, transmitting a Notice of Violation.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original Signed by Roy J. Caniano

Cynthia Pederson, Director  
Division of Nuclear Materials Safety

License No.: 34-24887-01  
Docket No.: 030-29809

bcc w/ltr dtd 09/26/96: PUBLIC

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September 26, 1996

United States Nuclear Regulatory Commission  
Washington, D.C. 20555

Attn. Document Control Desk

Subject: REPLY TO NOTICE OF VIOLATION LICENSE NUMBER: 34-24887-01

This is a response to the notice received at Trionix Research Laboratory, Inc, 8037 Bavaria Rd, Twinsburg, Oh 44087, dated August 28, 1996, and received on August 30, 1996. The letter referred to the inspection of our facility on July 26, 1996, by the NRC, and the follow up telephone conversation on August 08, 1996. (see attachment 1).

Pursuant to your request, the following contains our response and plans of action to the two (2) violations as listed on the Notice of violation form.

**Violation 1A**

**Reason for Violation**

The personnel listed on the nuclear license form, designated as responsible for the handling of radioisotopes have recently left Trionix.

**Corrective Steps Taken**

A new Officer was assigned to carry out the task of Nuclear Radiation Safety on August 9, 1996. He is responsible for continuation of the Radiation Safety program from this point on.

**Steps taken to avoid further Violations**

The corrective steps taken to prevent further violations, and to allow Trionix Research Laboratory, Inc to remain in compliance with federal regulations are as follows.

- 1.) An annual calendar has been generated, containing the maintenance schedule of the radiation safety program. The schedule includes training classes, radioisotope calibrator calibration, survey meter calibration, sources inventory, leakage tests, quarterly reviews, and any other such tests or training required by the NRC.
- 2.) A notice has been generated; this notice is posted in the hot lab and production areas, containing a brief summary of the jobs needing to be done with regards to nuclear safety regulations.
- 3.) Review all procedures in Radiation Safety Manual kept in the hot lab.
- 4.) There will be a quarterly review conducted by the Radiation Safety Committee. Part of this review would be to check that all required radiation safety tasks for the quarter have been completed and documented.

We anticipate the implementation of the above steps will prevent the repetition of violation 1a (the above also apply to violation 1c. See 1c for further information.)

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**Date of full Compliance**

A quarterly review is scheduled for the week of September 23, 1996. The first meeting was held today September 25, 1996. The March 10, 1987 application, item 10 (Radiation Program) is being used as a guide for this quarterly review.

**VIOLATION 1B**

**Reason for Violation**

The personnel listed on the nuclear license form, designated as responsible for the handling of radio-isotopes have recently left Trionix.

**Corrective steps Taken**

Two extremity monitoring finger badges were ordered from Landauer on Aug 8, 1996. The badges were received, and placed into immediate use upon arrival on Aug 10, 1996 (see attachment 2).

**Steps Taken to avoid further Violations**

This corrective measure will continue to be followed to avoid further violations in this aspect of nuclear safety. Any employee handling an isotope is required to utilize the extremity monitoring finger badges.

**Date of full Compliance**

The first two extremity monitoring finger badges were received at Trionix Research Laboratory on August 10, 1996 (see attachment 3). These badges will continue to be utilized, and exchanged for new badges with Landauer on a monthly basis, per regulations.

**VIOLATION 1C**

**Reason for Violation**

The personnel listed on the nuclear license form, designated as responsible for the handling of radio-isotopes have recently left Trionix. Because of Personnel changes this was over looked

**Corrective steps Taken**

The Victoreen Survey Meter, Model 290, was recalibrated on July 29, 1996 by Victoreen, Inc. (see attachment 4)

**Steps Taken to avoid further Violations**

The formation and distribution of the yearly calendar ( as noted in Violation 1a,, Steps Taken to avoid further Violation, section 1) will include the calibration dates for the Victoreen survey Meter. The calibration of the meter will also be included in the quarterly review ( as noted in Violation 1a, Steps Taken to avoid further Violation section 4) to insure it is not bypassed by the nuclear radiation safety officer.

**Date of Full Compliance**

The Victoreen Survey Meter, Model 290, was recalibrated on July 29, 1996 (see attachment 4).

**VIOLATION 2**

**Reason for Violation**

The former employee responsible for ordering the Gadolinium source did not realize Gadolinium requires an NRC license. He did however, obtain a state license for the usage of the source. In addition, Isotope Products sent the Gadolinium (Gd-153) sources without verifying our possession of an NRC license.

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**Corrective Steps Taken**

On August 16, 1996, Toye L. Simmons (NRC inspector), telephoned and notified Trionix Research Laboratory to take the Gadolinium (Gd-53) off the production floor and place these specific sources into the isotope radiation lead vault until such time as Trionix receives an amendment allowing the use of Gadolinium. This request was immediately complied with, and such compliance will continue until such time as the amendment to license is granted.

**Steps Taken to Avoid further Violations**

With the assignment of the new Radiation Safety Officer, this violation will not occur again. The Radiation Safety Officer will maintain control of all sources arriving at the facility. It is the responsibility of the Radiation Safety Officer to ensure that any and all sources/isotopes utilized by Trionix are properly licensed by both federal and state regulatory commissions. The quarterly review includes a check of the sources and licensure to ensure compliance with all regulations.

**Date of full Compliance**

On August 14, 1996 Trionix applied for an amendment to our NRC license control number 301728. Trionix is not now using, nor intends to utilize, any of the Gadolinium sources (Gd-153) until such time as the amendment to the license by the United States Nuclear Regulatory Commission is granted. (Ref: Violation 2, part 2).

I believe that this response letter should answer all violations completely, however, if you have any further questions please do not hesitate to contact me via telephone at your earliest convenience. I will be looking forward to your reply.

Sincerely,



Chun Bin Lim Ph.D.  
President and CEO,

copy to:           Regional Administrator  
                      Region 111  
                      801 Warrenville Rd.  
                      Lisle, IL 60532-4351

enc. (4)

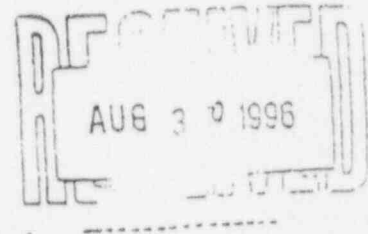
1. NRC inspection and notice of violation.
2. Purchase order, Landauer, for extremity monitoring finger badges.
3. Proof of receipt of Landauer extremity monitoring finger badges.
4. Report on Victoreen Survey Meter Calibration.
5. Calendar.



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

Attachment 1  
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August 28, 1996



Chun B. Lim, Ph.D., President  
Trionix Research Laboratory  
8037 Bavaria Road  
Twinsburg, OH 44087

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Dr. Lim:

This refers to the inspection conducted on July 26, 1996 at Trionix Research Laboratory in Twinsburg, Ohio. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with Messrs. Koval and Rappoport. This also refers to our discussion of the inspection findings by telephone on August 8, 1996.

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 with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements and observation of activities in progress.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). A written response is required. Violations No. 1 and 3 are repeat items. In your response to these violations, please describe why your proposed corrective action is expected to be more successful in preventing future or similar violations than the corrective action specified in your April 19, 1991 response.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

Cynthia D. Pederson, Director  
Division of Nuclear Materials Safety

License No.: 34-24887-01  
Docket No.: 030-29809

Enclosure: Notice of Violation

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