

MATERIALS LICENSE

Amendment No. 05

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301984

Licensee

1. Trionix Research Laboratory

2. 8037 Bavaria Road
Twinsburg, OH 44087In accordance with letter dated
October 24, 19963. License Number 34-24887-01 is amended
in its entirety to read as follows:

4. Expiration Date November 30, 2002

5. Docket or
Reference No. 030-298096. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Technetium-99m

A. Any

A. 200 millicuries

B. Iodine-131

B. Any

B. 3 millicuries

C. Gadolinium-153

C. Sealed sources
(Isotope Product
Laboratories
Model 3410)C. Nine sources not
to exceed 1 curie
each

9. Authorized Use:

A. To be used for instrument calibration and for the purpose of testing radiation
imaging devices.B. To be used for gamma camera resolution, calibration, and testing as stated in letter
dated October 20, 1995.

C. To be used for research, development and testing of gamma cameras.

CONDITIONS10. Licensed material shall be used only at the licensee's facilities located at
8037 Bavaria Road, Twinsburg, Ohio.

0/1

270094

9611290001 961030
PDR ADDCK 03029809
C PDRCOPY 2 ML30
JAW

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-24887-01

Docket or Reference Number

030-29809

Amendment No. 05

11. A. The Radiation Safety Officer for this license is Vitaliy Rappaport.
- B. Licensed material shall be used by, or under the supervision of, Chun Bin Lim, Ph.D., Bruce Koval and Vitaliy Rappaport.
12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- C. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

COPY

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-24887-01

Docket or Reference Number

030-29809

Amendment No. 05

- E. Tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to Perform such services.
13. The licensee shall conduct a physical inventory every 6 months to account for all radioactive material received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.
14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Applications dated March 10, 1987, April 25, 1992 and August 14, 1996; and
- B. Letters dated May 18, 1987, April 10, 1991, October 20, 1995 (with attachments) and October 1, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Oct 30, 1996

By Robert R. Metcalf
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03221
Status Code: 0
Fee Category: 3P
Exp. Date: 20021130
Fee Comments: IN HOUSE CALIBRATION
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: TRIONIX RESEARCH LABORATORY, INC.
Received Date: 961025
Docket No: 3029809
Control No.: 301984
License No.: 34-24887-01
Action Type: Amendment

2. FEE ATTACHED

Amount: ~~-----~~
Check No.: ~~-----~~

~~-----~~ * ADDL INFO
301728-R9

3. COMMENTS

Signed
Date

D. Hersey
11-27-96

FEE NOT REQUIRED

B. LICENSE FEE MANAGEMENT BRANCH (Check appropriate boxes and enter /_/_/)

1. Fee Category and Amount: *3P*

2. Correct Fee Paid. Application may be processed for:

Amendment ~~-----~~
Renewal ~~-----~~
License ~~-----~~

3. OTHER ~~-----~~

Signed
Date

SC
11/4/96

NOV 07 1996

RECEIVED BY LFDOB	
Date	<i>Nov. 4, 1996</i>
Log	<i>Nov 1 III</i>
By	<i>SC</i>
Date Completed	<i>11/4/96</i>

1996 NOV -4 AM 9:22



October 24, 1996

Nuclear Material Licensing Section
United States Nuclear Regulatory Commission
Region III
801 Warendville Road
Lisle, IL 60532-4351
Attn.: Ms. Evelyn R. Matson
Re: Control # 301728

Dear Ms. Matson

Now that the Gadolinium (Gd-153) model 3410 source has been approved by the state of California, we would like to change the most recent amendment with the control # 301728 as follows:

To allow Trionix Research Laboratory the permission to use Gadolinium (Gd-153) model 3410 source with the limit of up to 9,000 mCi.

With Gadolinium (Gd-153) model 33410 source approved, Trionix will not need the Gadolinium (Gd-153) model 3411 source in the present amendment. Attached please find a fax note and letter showing that the Gadolinium (Gd-153) model 3410 has been approved. The letter has the registration number of the Gadolinium (Gd-153) model 4310 source.

Thank you for your time and assistance. If you have any questions please feel free to call me. We are in urgent need to get this amendment change processed.

Sincerely,

Bruce Kcval

Enclosures:
Department of Health Services Letter
Fax Note from Isotope Products

Copy: Chun Lim

Continuation of 301728
FEE NOT REQUIRED

Pm: 10-24-96

RECEIVED

OCT 25 1996

REGION III

301984

OCT 25 1996

TRIONIX RESEARCH LABORATORY, INC.

8037 Bavaria Road • Twinsburg, Ohio • 44087 • Telephone: 216-425-9055 • FAX: 216-425-9063

**Isotope Products
Laboratories**

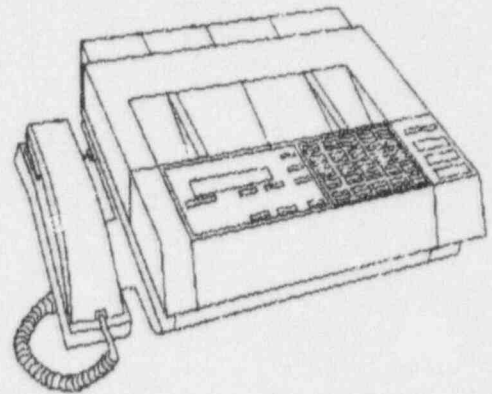
**1800 N. Keystone St., Burbank CA. 91504 U.S.A.
Tel (818)843-7000 Fax (818)843-6168**

Attn: Dr Rappoport

Company: Trionix
Fax no.: 216 425 9063

From: Len Hendrickson
Date: 16 Oct 96

Total pages: 2



Subject: Model 3410

The 3410 has been approved. I hope the attached letter will allow you to use the source you have.

The NRC can call Wesley to confirm. Regards.

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY

PETE WILSON, Governor

DEPARTMENT OF HEALTH SERVICES

601 NORTH 7TH STREET, MS-176

P.O. BOX 942732

SACRAMENTO, CA 94234-7320

(916) 445-1884

October 16, 1996



Michael Devine
Director of Engineering
Isotope Products Laboratories
1800 N. Keystone Street
Burbank, CA 91504

Dear Mr. Devine:

I have performed the final review of your Model A3410 line source and have found it to be acceptable for inclusion in the Sealed Source and Device Registry. The certificate number is CA406S182S. You will receive a copy of the certificate within the near future.

If you have any questions, please call me at (916) 445-1884.

Sincerely,

A handwritten signature in cursive script that reads 'David Wesley'.

David Wesley, Chief
Industrial Licensing Section
Radiologic Health Branch

NOV 08 1996

Bruce Koval
Trionix Research Laboratory, Inc.
8037 Bavaria Road
Twinsburg, OH 44807

Dear Mr. Koval:

Enclosed is Amendment No. 05 for your NRC Material License No. 34-24887-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;

301984

- b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,
Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

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

Enclosure: Amendment No. 05

DOCUMENT NAME: M:\03029809.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII <i>EM</i>	<input checked="" type="checkbox"/>							
NAME	EMatson:jaw								
DATE	10/30/96								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

October 29, 1996

Vitaliy Rappaport
Radiation Safety Officer
Trionix Research Laboratory, Inc.
8037 Bavaria Road
Twinsburg, OH 44087

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/24/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is a administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301984
License No. 34-24887-01