

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND,
OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA,
PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR
WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR
WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA,
NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH,
OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON,
AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS
TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item):

- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☒ C. RENEWAL OF LICENSE NUMBER 20-16325-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Radiation Monitoring Devices, Inc.
44 Hunt St.
Watertown, Mass 02172

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

44 Hunt St. and 50 Hunt St.
Watertown, Mass 02172

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION:

Dr. Derald Entine, President

TELEPHONE NUMBER
617-926-1167

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL:

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount
which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED:

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING AND EXPERIENCE:

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:

9. FACILITIES AND EQUIPMENT:

10. RADIATION SAFETY PROGRAM:

11. WASTE MANAGEMENT:

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3A AMOUNT
ENCLOSED \$ Prepaid

13. CERTIFICATION. (Must be completed by applicant): THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE
BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS
PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN,
IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION
TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Gerald Entine

Dr. Gerald Entine

President

11/15/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

< \$250K	<input checked="" type="checkbox"/>	\$1M-3.5M
\$250K-500K	<input type="checkbox"/>	\$3.5M-7M
\$500K-750K	<input type="checkbox"/>	\$7M-10M
\$750K-1M	<input type="checkbox"/>	> \$10M

b. NUMBER OF EMPLOYEES (Total for
entire facility excluding outside contractors)

30

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours)
ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE
PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit
it to protect confidential commercial or financial—proprietary—information furnished to
the agency in confidence)

☒ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE
			8604250253 851207 REG1 LIC30 20-16325-01 PDR	

November 15, 1985

Attn: Dr. Jack Davis
U. S. Nuclear Regulatory Commission
631 Park Avenue
King of Prussia, PA 19406

Reference: Byproduct Material License 20-16325-01

Attachment for Application for Material License

Item 5: SOURCES

- 1) Sources both sealed and unsealed as per Schedule 33.100 Col. 1 pertaining to Type B specific license of broad scope.
- 2) Americium 241 Sealed sources (Isotope Products Models PH-241, CF-241, PSC-241) Not to exceed 100 millicuries per source
- 3) Americium 241 Sealed source (Amersham Model AMR, AMC Series) Not to exceed 100 millicuries per source
- 4) Americium 241 Sealed source (NLS Model NER, NES Series, Gamma-tron GT-C, GT-CNP Series) Not to exceed 100 millicuries per source
- 5) Americium 241 Alpha source (Amersham Model AMM.1 to AMM.8, AMM.2401-04, AMR.22-.23) Not to exceed 10 millicuries per source
- 6) Americium 241 Alpha source (Isotope Products Model AFR-241 AF-241 Series) Not to exceed 1 millicuries per source
- 7) Americium 241/De Sealed sources (Amersham Model AMN Series or Nuclear Sources and Devices Gammatron AN-HP Series) Not to exceed 500 millicuries per source
- 8) Gadolinium 148 Alpha source (Isotope Products Models AF-148) Not to exceed 1 microcuries per source
- 9) Californium 252 Fission Fragment source Amersham Model CVN.1-.12, Isotope Products Model FF-250, N-252 Series Not to exceed 500 microcuries per source
- 10) Curium-244 Sealed sources (Isotope Products Models PH-244-1 to 20) Not to exceed 100 millicuries per source

Item 6: Purpose:

Testing of radiation detectors, research, and to process and manufacture items containing byproduct material for commercial distribution to specific licensees. A separate application for a class 3H license has been filed for distribution of items to general licensees.

Our research work involves the development of new nuclear detectors and instruments. We therefore use various isotopes to study the performance of these devices. In a typical experiment, a detector will be irradiated while its pulse height spectrum is examined, or a transmission or backscatter measurement will be made to assess the feasibility of a new technique.

No routine manufacturing of instruments containing byproduct material are conducted at this facility and virtually all laboratory personnel have in depth technical training. A typical instrument which we would manufacture is the Compuglass analyzer detailed in our 3G license application. This device which sells for \$30,000 to \$50,000 is made in such small quantity that all source handling is done directly by the personnel listed in item 7. In this case the source is removed from the vendor's housing with forceps and immediately placed into a specially prepared lead pig which is then sealed. Body film badges worn during this process in the past have shown no measurable exposure. Other instruments which we might envision manufacturing in the future will be of a similar nature.

Since the company has only 30 personnel at least eight of whom have received extensive training, all of these activities are conducted under the direct supervision of trained personnel.

Item 7: Responsible Individuals and Their Training

See Attachment A

Item 8: Training for Other Individuals

All laboratory personnel receive radiation safety training from their department head (listed in item 7) during their orientation period. This includes the topics delineated in the applicable sections of Part 19.12 and involves details about which sources they may use, proper procedure for source handling, source control responsibilities, health hazards and film badge requirements. In addition, group meetings are held at least annually at which the radiation safety officer reviews general procedures, and updates the staff on the special aspects of any sources recently acquired.

Unannounced inspections are also held during which the Radiation Safety Officer or one of the item 7 individuals walks through the facility to insure that the staff is maintaining a high level of compliance with the safety procedures.

Item 9: Facilities and Equipment

The laboratory has extensive nuclear instrumentation equipment including several pulse height analyzers, NIM electronic systems as well as both traditional and state-of-the-art nuclear detectors.

For the specific purpose of radiation safety monitoring the following equipment is available and in use for that purpose:

- a) Precision Radiation Instruments, Inc. Model 107C; One Beta Gamma Survey Meter with 0.04 mR/hr full scale.

- b) Ketex Inc. Gamma Survey Meter Model 304A; 0.1 to 100.0 mR/hr.
- c) Technical Associates Neutron Survey Meter Model PUG-1AB-PNS-20;
60 cps/n/sec/cm².
- d) Technical Associates Alpha Beta Survey Meter Model PUG-1AB-P11
Large area (1.75 inch) detector.
- e) RMD, Inc. Model CTC-4/B161 solid state beta gamma meter calibrated with
a New England Nuclear calibrated cobalt 57 source.

Item 10. Radiation Safety Program

All byproduct materials will be received in the radioisotope laboratory which is equipped with a lead storage container Nuclear Associates Model 52-885 or equivalent, handling tongs, work benches, sinks, and similar equipment. A locked cabinet, properly posted with the radiation symbol, is available for storage of radioactive material not in use.

All sources used at this facility will be sufficiently weak to allow handling by direct tongs and long forceps. No additional special handling equipment is appropriate.

All isotopes will be procured by the purchasing office only upon approval of the Radiation Safety Officer. Only when being used for experiment purposes will the byproducts be removed from their storage containers. All applicable sections of Part 20, Title 10 - Standards for Protection Against Radiation - will be observed. Surveys will be made with the survey meters or equivalent mentioned in Item 10 as detailed below.

All appropriate employees and visitors will be issued film badges which are read periodically (quarterly for gamma, monthly for neutron) by Landauer Corp. in accordance with section 620.202

Leak tests will be made of all gamma and beta sources above 100 microcuries both upon receipt and at least every 6 months thereafter. Alpha sources will be wipe tested every three months. Leak tests will be conducted under the direction of the Radiation Safety Officer by using a dampened cotton swab held by forceps while the source rests in the recess of its storage container. The swab will be analyzed on site under the direction of the Radiation Safety Officer with equipment capable of detection levels of 0.005 microCuries. The details of the leak test procedure are as follows:

The leak test program in-house is performed by RMD radiation safety officers and meets the general requirements of ANS, N542 standards. This procedure is outlined below

1. Wipe Test Procedure for Sealed Sources

a. Wiping Procedure: - Each sealed source is carefully swabbed with a cotton-tipped applicator moistened with methanol. The applicator is then counted by placing it close to (about 5mm) a large area (16mm dia.) CdTe detector connected to a PSP-1 and CTC-4.

b. Calibration Procedure - The sensitivity of the detector is verified by measuring a calibrated, but weak source (e.g., .003 microcurie) and recording the observed counts above background. This step is essential to demonstrate a sensitivity to at least .005 microcurie, the maximum permissible wipe. To achieve this sensitivity, it is essential to use a small blockhouse of lead bricks to reduce the background count rate to about 1 cps. Typical results give about 1 ct/nCi/s, so that a 100s count time gives ample sensitivity, a 5nCi wipe test would give 600 cts with a poisson error of ± 25 cts, i.e. 5%, and a

background of 100 cts.

c. Preshipment Wipe Test For Manufactured Items The leak test is applied to the source housing during the assembly of the device and to the sample tray, sample holder or other accessible surfaces nearest the source after the device is assembled. The records maintained on the leak-test previous to the shipment of the device include:

- o Identification of each source and device (manufacturer, model number, serial number, isotope quantity).
- o Identification of each customer (name, address, person to contact).
- o Radiation survey measurements.
- o Date of test.
- o Information on test methods used.
- o Leak-test results expressed in microcuries of radiation for each area wiped.
- o Identification of the individual who performed the test.

In the case of finding a leaking source, the source housing will be removed from the device. The source will be taken out of the source housing and will be placed in shielded and moderated drums.

2. Test Procedure for Surfaces

a. Survey Procedure: - Surveys of areas in which only sealed sources are used will be conducted every six months in conjunction with the wipe tests. Surveys of areas in which unsealed sources are used will be done every month in conjunction with the taking of the source inventory.

Each area in which only sealed sources are used will be surveyed with either a beta gamma or an alpha beta gamma meter to detect and radiation above background. Levels in the general work area above 1mR per hour will call for immediate investigation and above 2mR/hr will call for work stoppage until the source of the radiation is identified and the area certified safe by the Radiation Safety Officer. A formal log entry will be made of any such occurrences.

Each surface on which unsealed sources have been used since the previous in-house inspection will be surveyed with a large area alpha beta gamma meter listed above. This will include both the work surface itself as well as the floor area for a distance of three feet on all sides of the surface and also the nearest sink. If counts above 500 CPN/100 cm² are detected, an immediate investigation will be made to determine the source of the radiation. Above 1000 CPN/100 cm² the entire room will be surveyed and decontaminated. A formal log entry will be made of any such occurrences.

Item 11: Waste Management

Waste sources will be returned to the appropriate vendor, subcontractor or technical collaborators (eg., Harvard Medical School) if appropriate. All other waste sources will be disposed of through the commercial firm HMN Associates, Concord Mass.

6. Individuals Who Will Use or Directly Supervise The Use of Licensed Materials

Gerald Entine, Ph.D., President
Frank Sinclair, Ph.D, Senior Scientist
Michael R. Squillante, Ph.D., Director of Research
Ebrahim Afshari, M.Sc., Senior Engineer
Elisa Redler, MS, MBA, Marketing/Sales Manager
Kenneth R. Keller, MSEE, BSEE, Avalanche Product Manager
Peter Waer, BS, Marketing/Sales Engineer
Tom Hazlett, Manufacturing Manager

7. Radiation Protection Officer

Dr. Gerald Entine and/or Dr. Frank Sinclair and/or Dr. Michael R. Squillante

16. Training

Gerald Entine, Ph.D. - received his training in

- a) while on the job at Tyco Laboratories, Inc., Waltham, MA 02154 for a total of 4 years.
- in b) while at the same address he received on the job training for 4 years.
- in c) at University of Pennsylvania, PA for 2 years in both formal courses and on the job training.
- in d) at University of Pennsylvania, Phila. for 2 years in both formal courses and on the job training.

Frank Sinclair, Ph.D. - received his training in

- a) while at London University, U.K. and Instit. Lave-Langevin, Grenoble, France for a total of 3 years.
- in b) while at Brandeis University and at Radiation Monitoring Devices, Inc. he received on the job training for 7 years.
- in c) and d) at Brandeis University, Waltham, Ma. for 5 years in both formal courses and on the job training.
- in d) at Brandeis University, Medford, MA for 5 years in both formal courses and on the job training.

Michael R. Squillante, Ph.D. - received his training in

- a) while at Tufts University, Medford, MA for a total of 5 years.
- in b) while at Tufts University and at Radiation Monitoring Devices, Inc. he received on the job training for 8 years.
- in c) and d) at Tufts University, Medford, MA for 2 years in both formal courses and on the job training.
- in d) at Tufts University, Medford, MA for 2 years in both formal courses and on the job training.

Ebrahim Afshari, M.Sc. - received his training in a and b while at University of Lowell, Lowell, MA and as the Radiation Safety officer at Diano Corp. for a total of 4 years and in c and d while at Diano Corp. and Radiation Monitoring Devices, Inc. for 4 years in on the job training.

Elisa Redler, MS, MBA - received her training while on the job at Radiation Monitoring Devices, Inc., Watertown, MA for a total of 4 years.

Kenneth R. Keller, MSEE, BSEE - received his training during a formal Radiation Safety Course while on the job at Radiation Monitoring Devices, Inc., for six months.

Peter Waer, M.Sc., MBA - received his training in a and b while at University of Michigan, Ann Arbor, Mich. for a total of 2 years and in c and d while at Radiation Monitoring Devices, Inc. for 1 year in on the job training.

Thomas Hazlett - received his training in a, b, c, and d while on the job at Radiation Monitoring Devices, Inc. Watertown, MA for a total of 5 years.

17. Experience

Gerald Entine is experienced in handling sealed sources of Co-60, Cs-137, Am-241, I-128 and a number of beta sources such as Cl-37 in amounts up to 10 millicurie. He received this experience both at Tyco Laboratories for 4 years and while safety officer at Radiation Monitoring Devices for the last 9 years.

Frank Sinclair has extensive experience in handling sealed and unsealed sources as well as with research reactors. While at Brandeis University, he was the department representative on the University Radiation Protection Committee.

Michael Squillante has extensive experience in handling sealed sources and using research x-ray generators. This was obtained during his graduate work and during his professional career. He has worked with Co60, Cd109, Ba139, Cf252, Cs137, Am241 and Fe55 and has used a variety of x-ray fluorescence detectors, diffractometers, Laue cameras, Weissenberg cameras, etc. on x-ray generators from several manufacturers.

Ebrahim Afshari was the radiation protection officer at Diano Corp., a Division of Perkin Elmer Corp. which manufactures X-ray defraction equipment, and thus has extensive formal and on the job training.

Kenneth R. Keller, MSEE, BSEE has extensive experience in handling sealed sources while at Radiation Monitoring Devices, Inc. Some of the sources he has handled are Co60, Cs137, Am241 and Cd109.

Elisa Redler has extensive experience in handling sealed sources while at Radiation Monitoring Devices, Inc. Some of the sources she has handled are Co60, Cs137, Am241 and Cd109 up to amounts near one Curie.

Peter Waer has experience in handling sealed sources while at University of Michigan and at Radiation Monitoring Devices, Inc. Some of the sources he has handled are Co60, Cs137, Am241 and Cd109.

Thomas Hazlett has extensive experience in handling sealed sources while at Radiation Monitoring Devices, Inc. Some of the sources he has handled are Co60, Fe55, Cs137, I125, Am241 and Cd109 up to amounts near one Curie.

CONVERSATION RECORD

TIME

DATE

11/4/85

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☐ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Jerry Entine #

ORGANIZATION (Office, dept., bureau, etc.) Radiation Monitoring Device Co

TELEPHONE NO. 617-926

FIA AF SHARI

Device Co

1167

SUBJECT

Amendment for manufacturing license (Renewal)
New license for Distribution of Gen Lic.

SUMMARY

-01

- Type B Broad Lic
- Procedures for assembly
- Training
- F.I.R. Bridges
- Leak TEST
- Disposal
- What source/activity for specific lic:

-02

- What source/activity for general lic.
- Labeling
- Leak test analysis for custom
- Regulation to custom

ACTION REQUIRED

Will submit info supplied to HQ for registration
and new info in 2 weeks (11-18-85)

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Jack Davis

John Davis

ML10 11/4/85

ACTION TAKEN

"OFFICIAL RECORD COPY"

SIGNATURE

TITLE

DATE