L & L 28313

NRC FORM 313 (9-85) 10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB 3150-0120 Expires: 5-31-87

# APPLICATION FOR MATERIAL LICENSE 030-30902

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 HAMPSHIRE, 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)

X A. NEW LICENSE
B. AMENDMENT TO LICENSE NUMBER ____
C. RENEWAL OF LICENSE NUMBER ____

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

Warner-Lambert Company
810 Main Street
Cambridge, MA 02139

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

Same as item 2

8904240548 890111
REG1 LIC30
20-28313-01 PNU

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

TELEPHONE NUMBER: 1-617-491-2500

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. Addendum A

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. Addendum E

9. FACILITIES AND EQUIPMENT. Addendum D

10. RADIATION SAFETY PROGRAM. Addendum E

11. WASTE MANAGEMENT. Addendum F

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY New AMOUNT ENCLOSED $ 230.00

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 |
|---|---|---|---|
| Randall Cheney | J. Randall Cheney | Quality Control Manager | 10/24/88 |

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS: <$250K; $250K–500K; $500K–750K; $750K–1M; $1M–3.5M; $3.5M–7M; $7M–10M; >$10M

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

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 |
|---|---|---|---|---|
| APP | Dec 2I | 3P | 3P correct. Correction to be made to correct authorized use - RJ 4/89 | S. [signature] |
| AMOUNT RECEIVED | CHECK NUMBER | | | DATE |
| $230 | 1041 | | | 12/2/88 |

109890

PRIVACY ACT STATEMENT ON THE REVERSE

OFFICIAL RECORD COPY ML10

NOV 18 1988

## PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

Index of Addendums to the Application for a Radioactive Material License

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| F | Waste Management |

Addendum A

Radioactive Material

Element and Mass Number: Phosphorus - 32

Chemical and/or Physical Form: Aqueous nucleotides

Maximum possession: 1 millicurie

Addendum B

Purposes For Which Licensed Material Will Be Used

Licensed material used is incorporated in the GENE-TRAK Systems pre-packaged, pre-labelled, and pre-tagged kit for detection of microorganisms in test specimens. The test is an in-vitro diagnostic assay similar to clinical radio-immunoassays. The usual amount of isotope handled at one time will be 80 microcuries or less.

# Addendum C

## Individual Responsible for Radiation Safety Program and Their Training and Experience

the Radiation Safety Officer will be Susan K. Jessel.

It should be noted that Ms. Jessel has no previous experience with Radioactive Material.

Ms. Jessel will receive training at GENE-TRAK Systems, Framingham, MA. on December 15 & 16, 1988. The course will be conducted by GENE-TRAK Technical Service Personnel. GENE-TRAK Systems is authorized to provide training in radioisotope handling and safety procedures to students under NRC license # 20-19858-01, amendment 05, training to students. (expiration date February 1992)

The course is two days in duration and covers the following topics:

Principles and practices of radiation protection.
Radioactivity measurements, standardization and monitoring techniques and instruments.
Mathematics and calculations basic to use and measurement of radioactivity.
Biological effects of radiation.

A copy of the course agenda and Radiation Safety Manual is attached.

A certificate of training will be issued for Ms. Jessel upon completion of the training. The certificate of training will be submitted to the NRC.

In addition all laboratory personnel that will be using the GENE-TRAK assays will receive on-site training at Warner-Lambert Company upon issuance of the license. The training will consist of two days and is conducted by GENE-TRAK personnel. The training is similar to that offered to Ms. Jessel. A certificate of training will be issued to each laboratory staff member upon completion of the on-site training.

*GENE-TRAK* Systems

Schedule of In-House Training

Day 1

A.M.

Introduction to Gene-Trak Systems
Review the agenda
Review of the assay protocol
Start assay procedure, filter pre-prepared samples
Discussion of the principles of the procedure will
    accompany each step of the procedure

P.M.

Introduction to radioactivity
Biological effects of radiation
Recordkeeping and regulatory requirements
Viewing of a video tape on radiation protection

Day 2

A.M.

Continue with the test procedure in the laboratory
Add Pre-Hybridization Solution
  Discussion of radiation protection
Add Hybridization Solution and Probe
  Continue discussion of radiation protection
  Perform recordkeeping tasks

P.M.

Radiation measurements and instrumentation
Count filters and review data
Clean-up and radioactive spill procedure

GENE-TRAK SYSTEMS

New York Avenue
Framingham, Massachusetts 01701
617-872-3113

# Radiation

# Safety

# Training

# Manual

Prepared by:

*GENE-TRAK* Systems
Technical Service Department

052088

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## Introduction to Radioactivity

Nuclear species are grouped into families having certain common characteristics. A **nuclide** is characterized by the exact nuclear composition. For example:

$$^{12}C,\ ^{16}O \text{ and } ^{131}I$$

all are nuclides.

Nuclides having the same atomic number (same number of protons), are called **isotopes**:

$$^{125}I,\ ^{127}I \text{ and } ^{131}I$$

all are isotopes.

An isotope is said to be radioactive if the atoms of that isotope are undergoing spontaneous disintegration. This process is known as **radioactivity**.

The general concept is that an unstable nucleus (parent), gives rise to a more stable product (daughter), through radioactive decay. The daughter may still be radioactive and decay again. The result is the transition of one nuclear species to another and the transformation of mass into energy.

There are several modes of radioactive decay. When a neutron is converted to a proton and electron, the electron is ejected from the nucleus and is called a **beta particle.** For example, phosphorus-32 is in an unstable state. In order to become a more stable molecule it must release energy. It does this by emitting an electron that takes with it excess energy. Energy is released in the form of kinetic energy and the energy imparted to the ejected electron. The beta particle has a spectrum of energy that is predicted and can only penetrated a small thickness of solid material.

In decay by **alpha emission,** the nucleus ejects an alpha particle which consists of 2 neutrons and 2 protons (a helium nucleus). Heavy radionuclides, such as uranium-238 and its daughter products undergo a series of alpha and beta decay events to transform into lighter, more stable nuclides. Although very energetic, alpha particles have a very short range in solid material.

Atomic and nuclear processes often result in the emission of electromagnetic radiation such as **x-rays** or **gamma rays**. Electromagnetic radiation is a packet of energy called a **photon**. A photon has no mass or charge and travels at the speed of light. Because of these characteristics, x-rays are deeply penetrating but transfer little energy.

The above modes of radioactive decay are described as **ionizing radiation.** Ionizing radiation is any form of radiation that can directly or indirectly ionize molecules in its path. **Directly ionizing radiation** consists of particles having sufficient energy to produce ionization by collision. Beta particles are the major class of directly ionizing particles, e.g. $^{32}P$, $^{14}C$, $^{3}H$. **Indirectly ionizing radiation** consists of uncharged particles, such as gamma rays and x-rays that can produce an ion pair.

The activity of radioactive material is expressed in terms of the **Curie (Ci).** 1 Curie is equal to $2.22 \times 10^{12}$ **disintegrations per minute.** 1 microcurie (1 uCi) = $2.22 \times 10^{6}$ DPM.

The **half-life** is the length of time it takes for one half of the atoms to decay to a more stable form. Therefore, the rate of emission of beta particles is directly proportional to the number of radioactive atoms present. Example:

> $^{32}P$ has a half-life of approximately 14 days. If a probe solution contains 100 uCi on day 1, how many days must pass until there are 75 uCi remaining?
>
> 7 days.
>
> If 50%, or 50 uCi will be gone after the end of 2 weeks, then 25% or 25 uCi will be gone at the end of 1 week.

The maximun thickness of a substance through which a beta particle will penetrate is referred to as the **range**. The range is related to the density of the material so that if one knows the range in a material of 1 unit density we can divide by the new material density to determine the range. Example:

$^{32}P$ has a range of 0.8 cm in a material with a density of 1.0 gm/cm$^3$ (ie. water and soft tissue). If the density of glass is 2.3 gm/cm$^3$, what is the range of $^{32}P$ in glass?

$$\frac{0.8\ \text{cm}}{1.0\ \text{gm}/\text{cm}^3} = \frac{X}{2.3\ \text{gm}/\text{cm}^3}$$

therefore: $X = 0.35$ cm.

## Biological Effects of Radiation

Radiation can cause injury to living cells by transferring energy to molecules with which it interacts. Ionizing radiation disrupts the molecular structure by stripping the orbital electrons from the electron shells. The amount of cell damage is directly proportional to the amount of ionizing radiation. Some repairing occurs, however the unrepaired damage can accumulate resulting in permanent damage to organs and tissue or cancers.

Effects of ionizing radiation depend not only on the amount of energy involved but the location, extent of the region exposed and the duration of the exposure. Radiation is different from other harmful agents, ie. heat, noise, cold, etc., as we can sense these. Radiation has no direct sensory warning.

That's why limits on radiation exposure have been developed. They are derived from epidemiological and laboratory data on the relationship between the radiation exposure and the expected biological effect.

The **absorbed dose** is the amount of energy transferred to the matter divided by the mass of that matter. The absorbed dose can be different in various regions of the body. **Rad**, the radiation absorbed dose, is the term used to describe the absorbed dose.

$$1 \text{ rad} = 6.24 \times 10^7 \text{ MeV/gm}$$

Note: The basic unit of energy is the electron volt (eV). One eV is the amount of energy acquired by an electron when it accelerates through an electrical potential of one volt. $1.0 \text{ MeV} = 10^6 \text{ eV}$.

The **dose equivalent** is the basic quantity in radiation protection. The injury produced depends on the amount of energy imparted on matter. Some types of radiation produce greater effects than others with the same amount of energy imparted, for example, an alpha particle produces more injury than an electron. These differences are mainly due the mass of the particles. To provide for these differences the concept of **relative biological effectiveness (RBE)** was developed. The RBE for alpha particles is 20, for neutrons it is 10, and for x-rays, gamma rays and beta particles it is 1.0.

The **rem** is the unit of dose equivalent and is calculated by multiplying the rad by the RBE. In the case of $^{32}P$ the rem is equal to the rad and 1 rem is equal to 1000 millirem (mrem).

$$1 \text{ rem} = 1 \text{ rad} \times \text{RBE}$$

Different parts of the body are more or less sensitive to radiation than other parts. Radiation effects the most rapidly growing tissues first and foremost, ie. lens of the eye, intestinal lining, hair follicles and gonads.

Limits on radiation exposure have been developed by the United States Nuclear Regulatory Commission (NRC) and are printed in the Code of Federal Regulations, Title 10, Chapter 1, Part 20. Some of the more important ones are:

| | |
|---|---|
| Whole body, (including gonads, lenses of the eye and red bone marrow). | 5.0 rem/yr |
| Skin | 15 rem/yr |
| Hands | 75 rem/yr |
| Pregnant women (with respect to the fetus). | 0.5 rem/yr |

It is sometimes easier to appreciate hazards when one compares estimated loss of life expectancy from health risks. The folowing have been derived by the NRC, Office of Standards and Development, 1980**.

| Health Risk | Estimated average days of life lost |
|---|---|
| Smoking (1 pack/day) | 2,370 (6.5 years) |
| Overweight (20%) | 985 (2.7 years) |
| Auto accidents | 200 |
| Alcohol consumption (U.S. average) | 130 |
| Safest job (teaching) | 30 |
| Natural background radiation | 8 |
| Medical x-rays | 6 |
| 1 rem occupational dose* | 1 |
| 1 rem/yr, 30 years | 30 |
| 5 rem/yr, 30 years | 150 |

* industrial average is 0.34 rem/year.

** Miller, B., 1986, Laboratory Safety: Principles and Practices; American Society for Microbiology.

The quantities of radioactive material used in the performance of GENE-TRAK assays are well below what is necessary to cause any type of immediately detectable effect. Of more concern is the potential long term effects that can result from chronic exposure to even low levels of radiation. At the present time there is no threshold dose for these long term effects. Although the risk is small, common sense tells us that radiation exposure in the lab should be kept "As Low As Reasonably Achievable". This **ALARA** concept has been adopted by the NRC and cannot be overemphasized!

## Radiation Protection

As stated earlier, the standards for radiation protection are formulated by the NRC Code of Federal Regulations, Title 10, Part 20, but it is much easier to remember and adopt the ALARA concept. Regardless of the limits of radiation exposure, it should be maintained that the general policy is to avoid any unnecessary exposure to ionizing radiation.

Exposure to radioactivity can be classified as either **internal** or **external exposure.** Internal exposure comes from inhalation, injestion, or penetration of a radioactive material (e.g. absorption through the skin). Some basic rules for avoiding internal radiation doses are:

> Do not eat, drink or smoke in the laboratory to avoid accidental injestion.
>
> Wear protective clothing and gloves to protect the skin and avoid possible absorption of radioactive material.
>
> Wash your hands after performing procedures involving radionuclides.
>
> In certain chemical forms some radionuclides, e.g. $^{125}I$, are volatile. Prevent inhalation by using a fume hood and keep the source container capped when volitile chemical forms are possible.

Radiation exposure from external sources are those that deliver a dose from outside the body. Protection from external sources of radiation is accomplished through **Time, Distance** and **Shielding**. Obviously the longer one is exposed to the radiation source, the greater the number of particles will be incident on the body, therefore the greater the dose. We cannot feel radiation, so there is nothing to remind us of the exposure. One can limit the time, and therefore the length of exposure by knowing the procedures well and perfecting technique.

By increasing the distance between you and the source you can also limit exposure. The intensity varies inversely with the square of the distance. Example:

What is the reduction in exposure when a radioactive source is move from 10 cm to 100 cm?

The distance is increased by a factor of 10, therefore our equation reads as follows:

$$\frac{1}{d^2} = \frac{1}{10^2} = \frac{1}{100}$$

By moving our source by a factor of 10 we have reduced our exposure 100 times. In other words, the number of beta particles incident on the skin will be $1/100^{th}$ the number at 10 cm.

Another means of reducing radiation exposure is to place a radiation-absorbing shield between yourself and the radionuclide. When working with $^{32}P$, the most commonly used type of shielding is Lucite plastic. Shielding isn't quite as simple as calculating the range of a particle in a particular substance. When a beta particle strikes a target it may result in the emission of x-rays from that target. These x-rays are known as **bremsstrahlung radiation**. The efficiency of the x-rays produced increases with increasing atomic number, therefore it is better to shield beta emitters with aluminum or plastics, rather than steel or lead.

Limiting the time of exposure, increasing the distance between you and the source and using a shield are all important things to consider while handling radionuclides. We must not, however, forget the the need for safe laboratory practices. Basic laboratory common sense cannot be overemphasized. Do not eat or drink in the laboratory; do not pipette by mouth; wear protective clothing; keep the work area clean and uncluttered; etc... These and other precautions are required by the NRC and are listed in your license application.

Monitoring devices may be recommended and individual users have a right to see reports from these devices at any time. Monitoring devices are more commonly referred to as **film badges**. These will not provide protection, however they are useful even if the risk of exposure is small. Their use insures that unexpected exposure does not go unnoticed.

Film badges themselves are typically a small piece of x-ray film. The film blackens as it becomes exposed to radiation in the same way x-ray film is used to take x-rays of ones body. The blackening is read on a densitometer and is proportional to the amount of exposure. Selective filters provide density differences. The different densities identify general energies and allow for the conversion of the film dose to a tissue dose. To be effective the badges must be worn whenever one is working with radionuclides. It must be worn by the individual only and not left in the radiation area when not worn.

## Radiation Measurement and Instrumentation

When radiation passes through matter it interacts with atoms and molecules by transfering energy to them. This results in either of two situations. 1. The energy is sufficient enough to strip an orbiting electron from the atom of a molecule. This is known as **ionization** and results in an ion pair (a negatively charged electron and a positively charged atom or molecule).
2. **Excitation** occurs when the electrons are disturbed enough to enter an excited state but not enough to be ejected from the atom or molecule.

The Geiger-Muller counter is a type of ionization chamber. It measures the amount of ionizing radiation. The GM tube responds to radiation by means of ionization induced electrical currents. A volume of gas or air is contained between two electrodes having different voltages. This results in an electrical field between the negatively charged cathode and the positively charged anode. Normally the gas is an insulator and there is no current flowing between the electrodes. However, when the gas is ionized by radiation the charged molecules are attracted to the cathode. This causes a momentary electrical current. The flow of electrons is picked up on an ampmeter where the amount can be read from a scale.

One uses a GM counter to conduct surveys of the work area to monitor for radioactive contamination. The survey meter should be present and operable at all times and should be used to check fingers and hands, clothing and the work area. It should also be used during spill clean up. Although radiation cannot be sensed we are fortunate to have an instrument such as this so that we can monitor its presence.

When radioactive material reacts with matter and causes excitation or ionization the molecules or atoms of the matter undergo recombination or de-excitation to release energy. Most of this energy is in the form of thermal energy. However, if the energy is released in the form of visible light the material is called a scintillator. An instrument that detects scintillation is known as a scintillation detector.

In scintillation counters used to count gamma rays, the scintillator is a sodium iodide crystal. The radioactive material emits radiation which hits the crystal. Energy in the form of visible light is released and the light energy causes a photocathode to release photoelectrons. The photoelectrons are attracted to a series of dynodes. Each dynode releases more and more photoelectrons and ultimately the number of photoelectrons in this cascade are directly proportional to the amount of radiation incident on the scintillator.

To count beta radiation, a scintillation cocktail is commonly used to convert the radiation into visible light. The light is captured by a photomultiplier tube which releases photoelectrons as described above. In some cases, however, radiation can be detected without cocktail. The electrons are emitted from the source at various speeds. Because some exceed the speed of light in a particular medium, they release energy in the form of visible light. This phemonenon is known as **Cerenkov Radiation**. When one counts the filter circles in a scintillation counter without cocktail the counts represent the Cerenkov Radiation and this is proportional to the beta radiation from the source.

Although these instruments give us readings in proportion to the amount of radiation emitted from a particular sample, the results are not necessarily the true amount of radiation emitted. Instruments that measure radiation each have particular **efficiencies** that they are capable of achieving. Although the efficiency is a function of the type of instrument itself, it is also related to the radionuclide it is measuring. As different radionuclides emit particles or photons at different intensities of energy, it follows that some emissions are more easily detected than others. It is important to know the efficiency of the radiation detector you are using as the source strength can be determined by the count rate of the detector. The following equation is used to convert **Counts Per Minute** to **Disintegrations Per Minute**:

$$\frac{\text{CPM}}{\text{Efficiency of the Detector}} = \text{DPM}$$

Example: The efficiency of the GENE-TRAK Beta Detector is 40%. If the digital readout displays 400 counts per minute for a filter used during a wipe test, what is the actual value in disintegrations per minute?

$$\frac{400 \text{ CPM}}{0.4} = 1000 \text{ DPM}$$

## Recordkeeping and Regulatory Requirements

In order for an individual to initiate a program that includes the handling of radioactive materials, one must obtain authorization from the Nuclear Regulatory Commission (NRC) or the appropriate state agency. The authorization is in the form of a license specific for the designated material at a specific site. The license is granted after an application has been submitted and its requirements have been met.

Although the specific sites where procedures involving radionuclides are performed are documented in the NRC license, these areas must be clearly posted as a caution to those that have access to the area. A **"Caution Radioactive Material"** plaque is required in a room or area where the radionuclide is stored or used. Stickers with the same warning must be used to appropriately label containers holding radioactive material. A sign of this nature indicates that the amount of radioactive material used is in the range of 10 - 100 uCi. Other warnings, such as "Caution Radiation Area" or "High Radiation Area" should not be used as these indicate that much greater quantities of radioactivity are present.

A radiation safety program is conducted under the authority of a **Radiation Safety Officer (RSO)**. the RSO is responsible for conducting a radiation safety program to insure that all users are aware af the risks, and know the responsibilities for the safe use of radionuclides. The RSO is also responsible for keeping appropriate records for inventory and disposal of radionuclides.

Although the RSO is responsible for overseeing the radiation safety program, individual users are responsible for both complying with the regulations set fourth by the governing agency and the safe use of the radionuclide by himself and others in the facility.

Appropriate and accurate recordkeeping cannot be over emphasized!!!!!!! Your records are important legal documents and provide proof of compliance with your license as well as provide for effective administration of the radiation protection program.

__Receipt of radionuclides.__

Upon arrival, the radiation safety officer is responsible for inspecting the package to insure that it has not been damaged during shipping. A measurment of the amount of radiation emitted from the package is taken to insure that the contents are intact. In addition, wipe tests on both the package and the source container are performed to determine whether or not the radiation emitted, if any, is due to the source itself or is a result of removable contamination. See Appendix A.

__Inventory.__

It is important to keep track of the total amount of radionuclide on hand at any one time. As your license restricts your facility to a limited quantity, a record of your inventory is important so that you will not exceed your limit. Total inventory includes both the unused portion of the radionuclide as well as the solid radioactive waste being held for decay. See Appendix B.

__Dosimetry Reports.__

If dosimetry badges are recommended by the governing agency and a film badge service is established, periodic reports will be sent and should be made available for all users to see and inspect. The reports generally include the exposure for the given period (i.e., one month), quarterly exposure, annual exposure, and accumulated occupational dose.

__Radiation Surveys.__

Radiation surveys in the form of wipe tests should be performed weekly. Several locations in the laboratory should be tested for removable contamination by rubbing a 100 $cm^2$ surface with a filter paper circle. The filter paper is then counted in either a scintillation counter or with the GENE-TRAK Beta Detector. Remember to convert CPM to DPM and determine the amount of radioactivity removed from the surface. Choose several locations in your laboratory that are likely to become contaminated, for example, the refrigerator door handle, waterbath handle, sink drain and bench top. In most cases the limit is 500 DPM per 100 $cm^2$ but keep in mind the ALARA concept. If survey results usually are close to background, but suddenly an area has jumped to nearly 500 DPM, perhaps that area is slightly contaminated. It can never hurt to clean a higher than usual area even though it is less than the limit. See Appendix C.

**Disposal Records.**

Solid and liquid waste disposal must also be accounted for. Because the quantity of radionuclide being used is low, in most jurisdictions liquid waste can be disposed of down a designated sink drain. There are, however, limits on liquid radioactive waste disposal. It is important to keep up to date records so that these limits are not exceeded. Solid waste, on the other hand, must be stored for a minimum of10 half lives before it can be disposed of. A record of the initial date of storage and the date of disposal must be kept on file. See Appendices D and E.

**Instrument Calibration.**

Your survey meter must be calibrated annually and the certificate of calibration should be kept on file. The company that will perform the calibration of your survey meter is designated in your Radioactive Material License application. Keep in mind that while your survey meter is out for calibration you must have a replacement on hand. GENE-TRAK will be happy to loan you a survey meter for the period that yours is out.

Your beta detector will be calibrated at the manufacturer and will be checked with standards during the installation. Periodically, standards will be sent to your facility. The standards are to be counted and the data sent to us to determine whether or not your instrument should be recalibrated. Again, GENE-TRAK will send you a loaner as necessary.

## Glossary of Terms

**Absorbed Dose**

The mean energy of ionizing radiation imparted per unit mass irradiated material at a point of interest.

**Absorbed Dose Rate**

Absorbed dose delivered per unit time.

**Absorption**

The process by which radiation imparts some of all of its energy to the material through which it passes.

**Activity**

The nuclear transformations occuring in a given quantity of material per unit time at a given time.

**Background Radiation**

Ionizing radiation arising from radioactive materials other than that directly under consideration. Background radiation comes from cosmic rays and other naturally occuring radioactivity that is always present.

**Beta Particle**

A charged particle emitted from the nucleus of an atom, having a mass and charge equal to that of an electron.

**Bremsstrahlung**

Secondary photon radiation produced by deceleration of a charged particle passing through matter.

**Cosmic Ray**

High energy particulate and electromagnetic radiation that originates outside the earth's atmospere.

**Curie**

A unit of activity. One curie (Ci) equals $2.22 \times 10^{12}$ disintegrations per minute.

**Decay**

The process by which and unstable nucleus spontaneously a charged particle or photon.

**Dose Equivalent**

The dose equivalent is used in radiation protection as an indication of the biological effect that will be produced in an irradiated tissue. The dose equivalent is the product of the absorbed dose in tissue (see "rad") and the radiation biological effectivness (RBE).

**Efficiency**

A measure of the probability that a count will be recorded when radiation is incident on the detector.

**Film Badge**

A packet of photographic film used for the approximate measurement of radiation exposure for personnel monitoring. The film may contain more than one film of differing sensitivities, or it may contain filters which shield parts of the film from certain types of radiation.

**Geiger-Mueller**

A type of ionization chamber which measures the electrical potential between two electrodes that is created by ionizing radiation.

**Half-life**

The time required for a radioactive substance to lose 50% of its activity through radioactive decay.

**Half-value Layer**

The thickness of any material that will reduce the intensity of ionizing radiation by 50%.

**Inverse Square Law**

The intensity of radiation at any distance from a point source varies inversely as the square of that distance.

**Ionization**

The process by which a neutral atom or molecule acquires either a positive or a negative charge due to the transfer of energy from a radioactive source.

**Ionizing Radiation**

Any electromagnetic or particulate radiation capable of producing ions as it passes through matter.

**Isotopes**

Nuclides having the same atomic number (same number of protons) but differing in the number of neutrons, and therefore in the massnumber. Almost identical chemical 0.properties exist between isotopes of a particular element.

**Quality Factor**

The linear energy transfer factor by which absorbed doses are multiplied to obtain a quantity that expresses the biological effectiveness of the absored dose.

**Rad**

The basic quantity that characterizes the amount of energy incident on matter. 1 Rad = $6.24 \text{ X}10^7$ MeV/gm.

**Rem**

A special unit of dose equivalent. The dose equivalent in rems is numerically equal to the absorbed dose in rads multipled by the quality factor.

**Relative Biological Effectiveness (RBE)**

The RBE is a factor used to compare the biological effectiveness of the radiation absorbed dose (rads) due to different types of ionizing radiation.

**Roentgen (R)**

A special unit of exposure refering to photons of electromagnetic radiation. 1 R equals $2.58 \times 10^4$ coulombs per kilogram of air.

**Scintillation Counter**

An instrument in which light flashes caused by ionizing radiation incident on a scintillator are measured.

**X-ray**

Penetrating electromagnetic radiation having wavelengths shorter than those of visible light. They are usually produced by bombarding a metallic target with fast electrons in a high vacuum. These photons originate from the extra nuclear part of the atom as opposed to a gamma ray which originates from the nucleus.

# RADIOACTIVE SHIPMENT RECEIVING/INSPECTION REPORT

1. Isotope: ____________ Total number of uCi: _________

   Date rec'd: _______ Time rec'd: _______ P.O. #.__ ______

2. Visual Inspection of Vendor's Shipping Carton. If the shipping carton is damaged, contact the RSO immediately.

   Intact __ Punctured ___Wet ____Crushed ____Other ______

3. Vendor's Stated Radiation On Shipping Carton Label (s). _____

   Note: total in microcuries.

4. Closed Shipping Carton Radiation Scan

   a. meter identification: _________
   b. background count (BKG): _________ mRem/hr
   c. activity at 1 meter: _________ mRem/hr
   d. activity carton surface: _________ mRem/hr

   NOTE: if C exceeds 10 mRem/hr or D exceeds 200 mRem/hr, notify the RSO IMMEDIATELY!

5. Open Cartons(s). Total number of vials: __________

6. Do the order and vials agree as to:

   a. radioisotope ______yes, _____no, difference
   b. quantity ______yes, _____no, difference
   c. chemical form __ ____yes, _____no, difference

7. Wipe Results from:

   a. outer shipping carton ( cpm - bkg) x 2.5 = dpm

   b. source container ( cpm - bkg) x 2.5 = dpm

8. Survey results from packaging materials and empty shipping carton(s) _______mRem/hr.

   If contamination is detected, its source must be located and the RSO notified.

9. Disposition of packaging materials ______________

   Disposition of source container(s) ______________

10. If NRC/carrier notification is required, log the following:

    Time _____ Date: _________ Person(s) Notified: ____________

Received/inspected by: ________________Date:_________

P-32 INVENTORY LOG

| Date | uCi Received | uCi Drain Disposed | uCi Added to Solid Waste | Prev. Week Less Decay | Current Quantity |
|---|---|---|---|---|---|
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# WIPE TEST RECORD

| DATE | BACKGROUND (dpm) | LOCATION NO.* | WIPE TEST RESULT (cpm) | Net dpm/ 100 $cm^2$** |
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| *Location No. | Location |
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| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |

**
Net dpm/100 $cm^2$=
(Total cpm/100 $cm^2$ - Background) x 2.5

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# DISPOSAL RECORD FOR 32P LIQUID WASTE RELEASED INTO THE SEWERAGE SYSTEM

| | DATE | VOLUME | uCURIES | OPERATOR |
|---|---|---|---|---|
| 1. | | | | |
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| 25. | | | | |

When data has been entered on line 25, contact the RSO.

Appendix E

# SOLID WASTE DISPOSAL RECORD

| DATE PUT AWAY FOR DECAY | DATE DISPOSED AS REG. TRASH | SURVEY METER READING (mRem/hr.) | | RADIATION SYMBOLS REMOVED (Checked) |
|---|---|---|---|---|
| | | WASTE | BACKGROUND | |
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1. Sorenson, JA: Physics in Nuclear Medicine. Grune and Stratton, New York, New York. 1980.

2. Shapiro, J: Radiation Protection: A Guide for Scientists and Physicians. Havard University Press, Cambridge Massachusetts. 1981.

3. Lange, RC: Nuclear Medicine for Technicians. Year Book Publishers, Inc., Chicago, Illinois. 1973.

# Addendum D

# Facilities and Equipment

A. FACILITIES

A diagram of the laboratory is appended.

B. EQUIPMENT

Diagnostic tests are completed on a membrane filter and results are determined by the use of the GENE-TRAK Beta Detector.

The Detector is model CTC-4 manufactured by Radiation Monitoring Devices, Inc., 44 Hunt Street, Watertown, Massachusetts 02172. Performance of the Detector will be routinely checked in accordance with the GENE-TRAK Systems quality control procedure.

A geiger counter, such as a Ludlum 2 or 3 or equivalent, will be used to survey incoming packages and the work area. Calibration of the survey meter will be performed annually and after service and repair by:

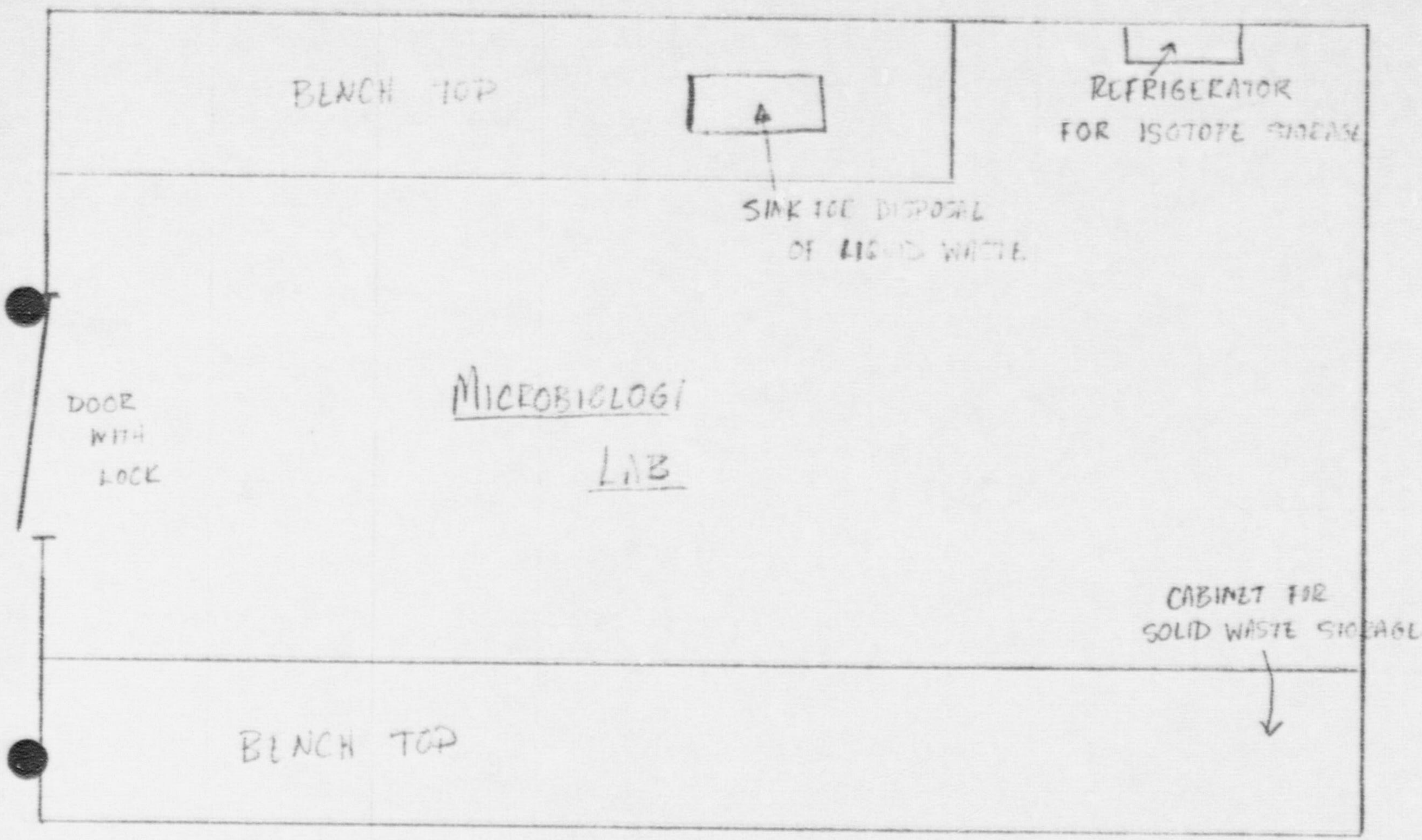
Ludlum Measurement Inc.
Sweetwater, Texas

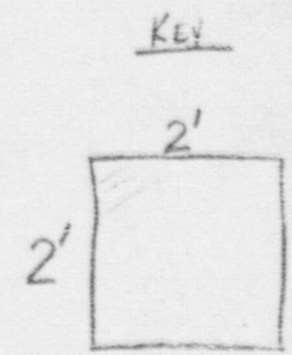
Personnel monitoring devices will be worn when performing the GENE-TRAK assay. Monitoring will include use of a beta-gamma film badge supplied and processed monthly by:

R. S. Landauer, Jr, and Co.

Shielding composed of one-half inch thick lucite, will be used during handling and storage of the isotope.

WARNER LAMBERT
810 MAIN STREET
CAMBRIDGE, MA 02139



# Addendum E

## Radiation Safety Program

A. Radiation Safety Officer

The RSO is responsible for the following:

1. Maintaining the radioactive material license in a compliance state.

2. Providing training of personnel to insure that safe procedures in the laboratory are practiced.

3. Providing consultation to management and radiation workers on all matters relating to radiation safety.

4. Be available to respond to any radiation emergency.

5. Reviewing all proposed procedures to insure that staff personnel will not become unnecesarily exposed to radiation. In addition, the RSO will insure that maximum permissable concentrations in air and water are within acceptable limits.

6. Insuring that the following documents are properly posted in the laboratory:

   a. Radioactive Material license and all supporting documents
   b. Appropriate state regulations or NRC Parts 19 and 20
   b Notice to Employees,
   d. Emergency Procedures

7. Advising radiation workers of any unusual procedures which they must employ in order to reduce unnecessary exposure. Also, advising workers of the location of radioactive material, and their responsibilities with regard to the safe use of radioactive materials.

8. Preparing any requests for license amendments.

9. Conducting a monthly physical inventory of all radioactive material to insure that possession limits are not exceeded.

B. Health Physics Surveys

On a weekly basis, the RSO will conduct a radiation safety survey of all areas where radioactive materials are used or stored. The surveys will include the following:

1. A survey of the work area by means of wipe tests. Wipe tests will be conducted using 25mm diameter filter paper circles. For each test, a 100 $cm^2$ area will be wiped, and results determined by counting filters in the Model CTC-4 Beta Detector. This instrument has a counting efficiency for Phopshorus 32 on dry filters of 0.4. Results will be recorded as disintegrations per minute (DPM). Permissable contamination levels have been establlished at 500 dpm per 100 $cm^2$. Contamination detected in excess of this level will be reported immediately to the responsible user who will insure that appropriate decomtamination is achieved. Follow-up reports will be submitted to the RSO accordingly.

   A standard pattern of wipe tests will be performed weekly in all areas of possible contamination, including benchtop(s), floors, refrigerator door handle, water bath cover, sink used for disposal of aqueous phosphorus -32 waste.

2. Review radioactive material storage areas to insure that materials are properly shielded, stored in double containers and properly labelled.

C. Authorized Users

The authorized user will be responsible within the department for the daily on-site management of radiation safety. They will report directly to the RSO who has overall responsibility if any of the following occurs:

1. Spill of radioactive material
2. Suspected overexposure of personnel
3. Malfunctioning radiation detection equipment
4. Contaminated shipment of radioactive material
5. Any other conditions that may result in unnecessary radiation exposure.

D. Procedures for Ordering Radioactive Materials

Prior to placing an order, the inventory will be reviewed to insure that possession limits will not be exceeded. The RSO will review these inventories and related procedures on a monthly basis.

During normal working hours, carriers will be instructed to deliver radioactive material packages directly to to the receiving department. There will be no after hour deliveries.

Incoming shipments will be examined visually. If the shipment appears wet or damaged, the RSO will be notified immediately.

The RSO will provide their office and home telephone numbers for any authorized user, and the numbers will be available in the laboratory.

## E. Procedure for Safely Opening Packages Containing Radioactive Materials

1. Gloves will be worn to prevent hand contamination.

2. Packages will be visually inspected for any sign of damage (i.e. wetness, crushed, etc) If damage is noted, the procedure will be stopped and the RSO notified.

3. The external surface of the outer package will be surveyed with the survey meter and the results recorded. If a surface exposure rate of greater than 10 m REM/hr is obtained, the procedure will be stopped and the RSO notified.

4. The outer package will be opened in a restricted area in accordance with the manufacturer's directions (if supplied), and the packing slip removed. The inner package will be opened and the contents verified by comparing requisition , packing slip and label on the bottle. The final source container will be checked for breakage of seals or vials, loss of liquid, discoloration of packing materials, etc. The possession limits will be checked to insure they are not exceeded.

5. A wipe test will be performed on the outer surface of the final source container and results recorded. Contamination in excess of 500 dpm per 100 $cm^2$ will be reported to the RSO.

6. Packing materials will be surveyed with the survey meter and results recorded before disposal.

F. General Rules for the Safe Use of Radioactive Material

1. laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.
2. Disposable gloves will be worn at all times while handling radioactive materials.
3. There will be no eating, drinking, smoking or application of cosmetics in any area where radioactive material is used or stored.
4. There will no storage of food, drink or personal effects with radioactive materials.
5. Radioactive waste will be disposed of only in specially designated receptacles.
6. No pipetting by mouth will be permitted.
7. Radioactive solutions will be confined in covered containers, plainly identified and labelled with name of compound, radionucleotide, date , activity and indication level , if applicable.
8. Radioactive materials will be locked when personnel are not present.
9. Emergency notification home telephone numbers will be posted in the laboratory.

G. Personnel Training Program

The personnel training program will be given to all personnel who work with radioactive materials. The training will be given in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to insure that all personnel receive proper instruction including:

1. Areas where radioactive materials are used or stored.
2. Potent hazards associated with radioactive materials.
3. Radiological safety procedures appropriate to their respective duties.
4. Pertinent regulations and terms of Radioactive Material License.
5. Rules and regulations of the license.
6. Their obligation to report unsafe conditions.
7. Appropriate responses to emergencies or unsafe conditions.
8. Their right to be informed of their radiation exposure.
9. Locations where the license is posted or made available notices and copies of pertinent licenses and license conditions (including applicable correspondence)

Personnel will be properly instructed as follows:

1. Before assuming duties with or in the vicinity of radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations or in the terms of the license.

## H. Emergency Procedures

### 1. Radioactive Spills

a. All persons in the area will be notified when a spill has occurred.

b. The spill will be covered with absorbent paper to prevent its spread.

c. Disposable gloves and tongs will be used to clean up the spill. The absorbent paper will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.

d. The survey will be conducted using a low-range thin-end window G-M survey meter . The area will around the spill, hands and clothing will be checked for contamination.

e. The incident will be reported to the Radiation Safety Officer.

f. Decontamination will be accomplished by scrubbing the spill areas with an industrial cleaner using disposable towels until readings on the survey meter indicate background levels have been achieved.

g. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

## ADDENDUM F

## WASTE MANAGEMENT

Management will insure that the volume of waste is minimized to the lowest practical level.

Short-lived radioactive material will be stored for decay until radioactive levels as measured in a low background area with a low-level survey meter with all shielding removed, have reached background levels, to insure that radiation levels do not exceed natural background. All radiation labels will be removed or obliterated and the waste will subsequently be disposed of in normal trash.

Liquid radioactive waste may be discharged into sanitary sewerage in accordance with the Regulations.

GENE-TRAK SYSTEMS

[?]1 New York Avenue
Framingham, Massachusetts 01701
617-872-3113

# CERTIFICATE OF TRAINING

This is to certify that, SUSAN JESSEL,
from WARNER-LAMBERT COMPANY,
received training in the performance of the GENE-TRAK Assay and its attendent use of Phosphorus-32 labelled material. The training was conducted at GENE-TRAK Systems, Framingham, Massachusetts. The training was conducted by GENE-TRAK Technical Services Department Personnel. The training was conducted on 12/15/88 & 12/16/88

The training covered the following topics:

a. Principles and practices of Radiation protection
b. Radioactivity measurements, standardization and monitoring techniques and instruments,
c. Mathematics and calculations basic to use and measurement of radioactivity, and
d. biological effects of radiation.

Signed: Bonnie Brasse

Date: 12/16/88

OFFICIAL RECORD COPY ML10

109890
12-30-88

NRC/Agreement State

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: -----
STATUS CODE: 3
FEE CATEGORY: ----------
EXP. DATE: 0
FEE COMMENTS: ----------

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: WARNER-LAMBERT COMPANY
   RECEIVED DATE: 881118
   DOCKET NO: 3030902
   CONTROL NO.: 109890
   LICENSE NO.:
   ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
   AMOUNT: $230.00
   CHECK NO.: 001041

3. COMMENTS

SIGNED EMW
DATE NOV 22, 1988

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /✓)

1. FEE CATEGORY AND AMOUNT: 3P $230

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ----------
   RENEWAL ----------
   LICENSE ✓

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

SIGNED S. Kimberly
DATE 12/2/88