NRC FORM 313 (7-96)
10 CFR 30, 32, 33 34, 35, 36, 39 and 40

U. NUCLEAR REGULATORY COMMISSION

APPROVED OMB NO. 3150-0120 EXPIRES: 7/31/98

Estimated burden per response to comply with this information collection request 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

LL 30442
030 - 34681
03620

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 JURISDICTIONS.

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)*
   Small Molecule Therapeutics, Inc.
   11 Deer Park Drive, Suite 116
   Monmouth Junction, NJ 08852

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   11 Deer Park Drive, Suite 116
   Monmouth Junction, NJ 08852

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   David A. Elsemore, Ph.D.

   TELEPHONE NUMBER
   732-274-2882

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 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 3M
    AMOUNT ENCLOSED $ 1900.

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, 36, 39 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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Prabhavathi Fernandes, Ph.D., CEO	[signature]	9 March '98

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NRC FORM 313 (7-96)

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MAR 11 1998

US Nuclear Regulatory Commission
Radioactive Material *New* License Application

Small Molecule Therapeutics, Inc.

11 Deer Park Drive, Suite 116
Monmouth Junction, NJ 08852
phone: 732-274-2882
fax: 732-274-0086

Company contact:
David A. Elsemore, PhD
phone: 732-274-2882 x107

March 1998

license application prepared with the assistance of
Wesley R. Van Pelt, PhD, CIH, CHP
Wesley R. Van Pelt Associates, Inc.
Paramus, NJ

Table of Contents

Question 5 - Radioactive Material Possession Limits

Element & Mass Number	**Chemical or Physical Form**	**Maximum Amount Possessed at Any One Time**	**Half Life**
Hydrogen-3	any	500 mCi	12.3 years
Carbon-14	any	30 mCi	5730 years
Sulfur-35	any	200 mCi	87.4 days
Phosphorous-32	any	100 mCi	14.26 days
Phosphorous-33	any	100 mCi	25.4 days
Iodine-125	bound to compounds (non-volatile)	200 mCi	60 days

Question 6 - Purpose for Which Licensed Material Will be Used

Small Molecule Therapeutics, Inc. was established in July 1997 and has about 20-30 employees.

Small Molecule Therapeutics, Inc. is a research and development organization which will use radioactive material in the course of research and development in molecular biology, biochemistry and biotechnology, including laboratory tracer experiments, cell/tissue culture, binding assays, high throughput screening, etc.

There will be no human use of radioactive materials conducted under this license.

There will be no iodination of compounds. All I-125 will be obtained as labeled compounds.

There will be no use of radioactivity in laboratory animals under this license.

There will be no commercial manufacturing or distribution of devices or products containing licensed radioactivity.

There will be no field studies involving dispersing radioactivity in the environment.

Decommissioning Funding Consideration

NRC regulation 30.35 requires decommissioning planning and funding assurance if license possession limits for radionuclides with half lives in excess of 120 days exceed certain activity levels. The following tables show all requested radionuclides with half lives more than 120 days. The sum of the ratios rule applies for more than one radionuclide. The evaluation makes use of the value R, defined in 10 CFR 30.35(a), which is the possession limit divided by the value in Appendix to 10 CFR 30. If the sum of the ratios is less than one, the licensee will be exempt from the requirements of 10 CFR 30.35(a)-(f).

Decommissioning Funding Calculation - Unsealed Activity				
Radionuclide	**Requested Possession limit, millicurie**	**Value in Appendix B to 10 CFR 30, millicurie**	**R**	**Ratio R Divided by 10^3**
Hydrogen-3	500	1.00	500	0.50
Carbon-14	30	0.10	300	0.30
			Sum of Ratios:	**0.800**

Consideration of Need for Emergency Plan for Responding to a Release

NRC regulation 10 CFR 30.32 (I) requires emergency plans for responding to a release when licensees have possession limits above the levels listed in Schedule C of 10 CFR 30.72. Applying the sum of the ratios rule for more than one radionuclide, the requested possession limits are well below the level requiring an emergency plan for responding to a release. Therefore the licensee will be exempt from the requirements of 10 CFR 30.32 (I).

Minimization of Contamination

According to NRC regulation 10 CFR 20.1406, applicants for a license after 20 August 1997 "shall describe in the application how facility design and procedures for operation will minimize to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize to the extent practicable, the generation of radioactive waste."

This license application contains many facility features and procedures that address the above concerns. These features and procedures are described in various sections of this application, some of which are summarized below:

1. All radioactive materials will be used by persons with training in radiation safety and experience or supervision in the safe use of radioactive materials. The use of radioactive material will be reviewed and approved by the Radiation Safety Officer.

2. Routine radiation contamination surveys will be done at a frequency of at least monthly.

3. Removable contamination above 300 dpm/100 cm^2 will be routinely cleaned up by lab personnel. This action level for clean-up is stricter than levels typically allowed for release for unrestricted use. For example, NRC guidance would allow removable contamination up to 1000 dpm/100 cm^2 to be released for unrestricted use (See "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," US Nuclear Regulatory Commission, May 1987.)

4. Radioactive material will be used in modern well-equipped laboratories with impervious bench tops and/or impervious trays or liners.

5. Preference will be given to short lived radionuclides such as I-125 over long lived radionuclides such as H-3 and C-14. This will allow reduction in any contamination by natural radioactive decay.

6. Non-radioactive objects will be segregated from the radioactive waste stream, thereby reducing the volume of radioactive waste needing management and disposal resources.

7. Short lived radioactive materials will be decayed in storage, thereby making further treatment or burial as radioactive waste unnecessary.

Question 7 - Individuals Responsible for Radiation Program and Their Training and Experience.

Radiation Safety Officer

The Radiation Safety Officer will be David A. Elsemore, PhD.

A copy of Dr. Elsemore's training and experience with radiation and radioactive materials is attached. Also attached is Dr. Elsemore's professional resume.

Dr. Elsemore will register for and take the following one-day courses which are part of the short course series in Radiation Safety given by Rutgers University, New Brunswick, NJ.

Radioisotope Laboratory Safety, 13 May 1998, RSSC51398
Radiation Protection Program Management, 15 May 1998, RSSC51598
Liquid Scintillation Counting, 18 May 1998, RSSC51898

Responsibilities of Radiation Safety Officer

The Radiation Safety Officer will have responsibility for maintaining required records and for implementing the radiation safety program. While maintaining this responsibility, the Radiation Safety Officer may delegate certain tasks to others. The responsibilities of the Radiation Safety Officer are as follows:

1. To assess radiological hazards and to prescribe and implement appropriate radiation safety precautions.
2. To ensure that the use of licensed material is by or under the supervision of individuals specifically listed on the Nuclear Regulatory Commission license.
3. To ensure that all users, when and where required by Nuclear Regulatory Commission regulations or license conditions, wear appropriate personnel monitoring equipment such as badge and ring dosimeters.
4. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.
5. To perform routine inspections of all laboratories using or storing licensed materials.
6. To ensure that the terms and conditions of the license are met, and that all required records are maintained.

Authority of Radiation Safety Officer

Dr. David A. Elsemore reports directly to Dr. Krishna Kodukula, Executive Director, who has senior management responsibility for the scientific staff at the facility. As such, the Radiation Safety Officer has the necessary authority for implementation of all necessary radiation protection actions.

The Radiation Safety Officer will approve all requests to order or otherwise acquire radioactive materials to ensure that the material may be possessed by authority of the license and that activity limits will not be exceeded.

Question 8 - Training for Individuals Working In or Frequenting Restricted Areas.

The following named individuals, called Authorized Radiation Users, will use or supervise the use of licensed radioactive materials:

Authorized Radiation User	**Radionuclides to be used by or under the supervision of Authorized Radiation User**
John Cantello, PhD	P-32, P-33, S-35
David A. Elsemore, PhD	P-32, P-33, S-35, all other radionuclides in order to perform duties as RSO
Weihong Hsing	H-3, C-14, P-32, P-33, S-35
Vladimir Khazak	P-32, P-33, S-35
Krishna Kodukula, PhD	H-3, C-14, P-32, P-33, S-35, I-125
Wei Liu	H-3, C-14, P-32, P-33, S-35, I-125
Yi Liu	P-32, P-33, S-35, I-125
Rolf Menzel	H-3, C-14, P-32, P-33, I-125
Jian Pang	P-32, P-33
James Pei	H-3, P-32, P-33
Patrick Romano	H-3, P-32, P-33, S-35
Hai Sheng	P-32, P-33, S-35
Jenny Wang	H-3, P-32, P-33, S-35, I-125
Alicia Warren	P-32, P-33, S-35
Weiren Zhang	H-3, P-32, P-33, S-35, I-125
Meg Zinda	P-32, P-33, S-35

Attached are Training and Experience Forms summarizing the training and professional and technical experience of these individuals related to their ability to safely use radioactive materials.

Persons with experience handling P-32 can also safely handle P-33 because of its identical chemical properties, similar half life, and lower (safer) beta energy.

Question 9 - Facilities and Equipment

Facilities

Small Molecule Therapeutics, Inc. will be located in a modern commercial building in Monmouth Junction, NJ. Its facility consists of scientific laboratories and offices and is located at 11 Deer Park Drive, Suite 116, Monmouth Junction, NJ 08852.

While Small Molecule Thereapeutics, Inc. has facilities on both the first and second floors of the two floor building, only offices are located on the second floor. All laboratories are located on the first floor. Radioactive material use and storage will be restricted to the first floor areas. Figure 1 shows the first floor plan with the designated locations where licensed material may be stored or used. Rooms designated for radioactive material use and storage are:

1. Rad Waste area (in Warehouse area)
2. Media Room
3. Tissue Culture One
4. Front Lab
5. Instrument Room
6. Middle Lab
7. Screening Room
8. Dark Room (Drk. Room)
9. Cold Room
10. Tissue Culture

There will be no radioactive use or storage in the areas designated as Closet, Office Area, and Bathrooms.

There will be at least one chemical fume hood available in the above labs for handling radioactive materials. Floors will be constructed of impervious materials such as vinyl floor tile to reduce absorption of any spilled materials and allow for easier clean up.

Radioactive waste for temporary storage and storage-for-decay will be stored in the Rad Waste storage area shown in Figure 1. The Rad Waste storage area is located in the warehouse and will consist of a secure segregated area bounded with 1-hour rated walls and a lockable door. Radioactive waste will be collected and packaged in the laboratory rooms and then moved into the Rad Waste storage area.

The facility is sprinkler protected in the event of fire.

Equipment

In addition to the fixed facilities described above, equipment of various types will be used for radiation safety purposes.

Clear Lucite plastic shielding will be used for the higher energy beta emitters such as P-32. Plastic shielding will be in the form of vial holders, self-standing body shields, storage boxes, etc.

Safety glasses (glass or plastic) will be utilized in the lab when handling P-32 to reduce the beta radiation dose to the lens of the eye.

Manual remote tongs and/or forceps will be available to manipulate radioactive materials so as to keep the dose to the hands as low as reasonably achievable.

Question 10 - Radiation Safety Program

Radiation Detection Instrumentation

The company has a Packard Top Count NXT Microplate scintillation and luminescence counter, model number C384V00. This or an equivalent liquid scintillation counter will be used to count samples for beta and electron capture radionuclides including hydrogen-3, carbon-14, phosphorus-32, phosphorus-33, sulfur-35, and iodine-125. The Radiation Safety Officer will use the counter to assay swipes from various radiological surveys. (Note that all of the above radionuclides are pure beta emitters except for iodine-125 which decays by electron capture. The liquid scintillation counting efficiency for iodine-125 is about 78% which is due to Auger electrons, conversion electrons and the gamma produced Compton electrons. For the pure beta emitters, the liquid scintillation counting efficiency ranges from 65% for tritium to 99% for P-32.)

Optionally, routine survey swipe samples may be sent to an outside contract lab for analysis for radioactivity. The outside laboratory, such as Teledyne Environmental Services, Westwood, NJ, will be licensed by the NRC or an Agreement State to perform such analyses.

The company will have radiation survey instruments each consisting of a hand-held battery-operated ratemeter with an end-window pancake-style Geiger detector probe. This type of Geiger probe has a typical window thickness of 1.7 mg/cm2 and an active open area of about 15 cm2. It has a typical background of 30 - 40 cpm and sensitivity range of 100 to 500,000 cpm. The detection efficiency of this probe for carbon-14 is nominally 5-10 percent. A Ludlum Model 44-9 probe and ratemeter, or an essentially equivalent Geiger survey meter, will be used to detect the presence and relative intensity of beta and electron capture radionuclides, including carbon-14, phosphorus-32, phosphorus-33, sulfur-35, and iodine-125. There will be at least one such radiation survey meter available in each lab actively using radioactive materials.

Labs using I-125 will have a thin sodium iodide crystal detector survey meter which is optimum for detecting the low energy photon radiation from I-125. A Ludlum Model 44-3 low energy gamma scintillation probe and ratemeter, or equivalent, will be available for labs using I-125.

Backup radiation survey instruments will be available when an instrument is off site for calibration or repair.

Radiation Detection Instrumentation Calibration

The liquid scintillation analyzer will be calibrated at least annually by a trained service technician under a service contract with the manufacturer.

The portable radiation survey meters will be calibrated annually and after repairs (other than minor repairs such as battery or cable replacement) by the manufacturer or by a reputable commercial calibration lab licensed to calibrate survey meters by the US NRC or an Agreement State. The calibration lab currently selected is Ludlum Measurements, Inc., Sweetwater, TX.

Personnel Monitoring

External Radiation Monitoring

Whole body and extremity dosimeters will be provided to individuals for whom personnel monitoring is required by 10 CFR 20.1502(a). Whole body dosimeter badges and ring dosimeters will be obtained from a commercial dosimetry vendor such as Landauer, Inc., Glenwood, IL or ICN Dosimetry Service, Cosa Mesa, CA. Any vendor selected by the licensee will be currently NVLAP accredited by the National Institute for Standards and Technology (NIST) for beta and photon dosimetry. Dosimeters will be exchanged and read out at least quarterly.

Persons who use millicurie quantities of iodine-125 (gamma emitter) or P-32 (high energy beta emitter) will be required to wear a badge dosimeter and ring dosimeter when working with this material.

Internal Radiation Monitoring (bioassay for tritium)

The requested possession limit for tritium in any chemical and physical form is 500 mCi. The ALI for tritium is 80 mCi. It is anticipated that individuals will routinely work with sub-millicurie quantities of tritium, and occasionally with stock reagent containers of up to 20 mCi each. Therefore, it is highly unlikely that any routine or emergency condition would result in uptake of anywhere near 8 mCi (10% of the ALI). Urine bioassays for tritium will therefore not be required for routine use. Tritium bioassays will be performed in the unusual event where greater than 20 mCi of tritium is released, spilled or grossly misused and an individual is potentially severely exposed via ingestion, body contact or inhalation.

The action levels for any urine bioassays will be determined by applying Nuclear Regulatory Commission Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," Revision 1, July 1993. Regulatory Guide 8.9 states that methods acceptable to the Nuclear Regulatory Commission staff are contained in ICRP Report No. 54, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation." ICRP 54 defines the Derived Investigational Level (DIL)[1] and Derived Recording Level (DRL)[2] and calculates values

[1] Investigation Level. Level of committed dose equivalent or intake above which the result is regarded as sufficiently important to justify further investigation. Investigation levels are defined for routine monitoring, IL_R, and for special or operational monitoring, IL_S. Derived investigation levels,

for each for both routine monitoring and special monitoring (i.e., following an incident in our case). The licensee will adopt the "special" ICRP 54 based action levels which are summarized in the following table:

Action Levels Following Urine Bioassay for Tritium				
Frequency	Tritium Concentration in Urine			
	Derived Investigation Level (DIL)		Derived Recording Level (DRL)	
	µCi/L	Bq/ml	µCi/L	Bq/ml
Special (following an incident)	**170**	6400	**57**	2100

Action will be taken if the measured urine concentration equals or exceeds either the DIL or DRL for special monitoring as follows:

- All tritium concentrations in urine greater than the DRL will be converted to an estimate of the Committed Effective Dose Equivalent for possible inclusion in the person's Total Effective Dose Equivalent as required by 10 CFR 20. (For reference, ICRP 54 gives the Committed Effective Dose Equivalent per unit intake of H-3 as 1.7×10^{-11} Sv Bq^{-1} = 0.063 mrem/µCi. Also, at a time of 1 day after intake, the predicted activity concentration normalized to unit intake is 2.2×10^{-5} uCi/ml per uCi intake.)

- Tritium concentration in urine greater than the DIL will initiate an investigation by the Radiation Safety Officer. The investigation will attempt to determine the source and circumstances of the exposure and recommend actions which would reduce or eliminate future exposures. As part of the ALARA program the Radiation Safety Officer will maintain a written record of the investigation and recommended actions. The exposed person will have subsequent urine bioassays at least weekly until the tritium concentration in urine falls to below the DRL.

DIL_R and DIL_S, are values of body or organ content or elimination rate that correspond to investigation levels, IL_R and IL_S. These values are calculated by means of defined models of intake, deposition, uptake, retention and elimination.

[2] Recording Level. Level of committed dose equivalent or intake above which the result is of sufficient interest to be worth keeping and interpreting. Recording levels are defined for routine monitoring, RL_R, and for special or operational monitoring, RL_S. Derived recording levels, DRL_R and DRL_S, are values of body or organ content or elimination rate that correspond to recording levels, RL_R and RL_S. The values are calculated by means of defined models of intake, deposition, uptake, retention and elimination.

- Tritium concentration in urine greater than 10 times the DIL will initiate all actions outlined above plus the following: Refer the person to medical personnel for recommendations regarding the need for therapeutic measures to accelerate removal of tritium from the body thereby reducing the radiation dose. (Such procedures might include increased drinking of fluids and use of diuretics.) Evaluate need to restrict person's potential for future exposure to assure the annual limit of 5 rem Total Effective Dose Equivalent is not exceeded. Evaluate the need to make reports to the NRC under 10 CFR 20.2202 and 20.2203.

Internal Radiation Monitoring (bioassay for iodine-125)

Regarding bioassays for persons using I-125, the licensee will conduct bioassays at frequencies based on principles described in Nuclear Regulatory Commission Regulatory Guide 8.20 (Revision 1, September 1979), "Applications of Bioassay for I-125 and I-131" when usage exceeds 10% of the Table 1 usage criteria. Table 1 describes the chemical/physical form (volatile or dispersible versus bound to a nonvolatile agent), type of operation, and quantity of activity in unsealed form above which bioassay is necessary. Regulatory Guide 8.20 describes bioassay procedures which "aid in determining the extent of an individual's exposure to concentrations of radioactive material." Regulatory Guide 8.20 is based on a Derived Air Concentration (DAC) of 5x10-9 μCi/cc for occupational inhalation exposure taken from the "old Part 20" Appendix B. However, the current "new Part 20" DAC for occupational inhalation exposure is 3x10-8 μCi/cc, **a factor of 6 less restrictive**. The licensee will adjust the Table 1 target levels of Regulatory Guide 8.20 by a factor of 6 to correct for the Nuclear Regulatory Commission's current relationship between DAC and dose. Thus, the licensee will institute thyroid bioassay **when use exceeds 10%** of the **adjusted** target values in Table 1 in Regulatory Guide 8.20. That is, the licensee will perform thyroid bioassays when usage exceeds values in the table below. We understand that "usage" according to Regulatory Guide 8.20 is defined as the cumulative amount in process handled by a worker during a 3-month period.

Activity Levels Above Which Bioassay for I-125 will be Performed		
	Activity Handled in Unsealed Form Making Bioassay Necessary	
Type of Operation	Volatile or Dispersible	**Bound to Nonvolatile Agent**
Processes in **open room or bench**, with possible escape of iodine from process vessels.	0.6 mCi	**6 mCi**
Processes with possible escape of iodine carried out within a **fume hood** of adequate design, face velocity, and performance reliability	6 mCi	**60 mCi**

If thyroid bioassay is required by the above table, equipment will be obtained and calibrated (see below), and thyroid bioassays will be performed on site. Thyroid bioassay will be done with a 2-inch diameter thin sodium iodide crystal scintillation probe connected to a single channel or multichannel analyzer set to the I-125 photon peak centered at 30 keV. Calibration will be done with a NIST traceable I-129 standard placed in a plastic neck phantom which simulates the geometry and attenuation of a human thyroid and neck. A correction will be made for the different photon abundances of I-129 (0.777 photons per decay) and I-125 (1.459 photons per decay) in the 25-35 keV energy region. Calibration will be done monthly, or at the time of the bioassay if bioassays are done less frequently than monthly. Thyroid bioassay results will be recorded in units of microcuries (or Becquerels) in the thyroid.

As an alternative to obtaining the above equipment, the licensee may outsource the thyroid bioassays to a contracting company or institution with the capabilities to do thyroid bioassays for I-125. The selected contractor will be licensed by the NRC or an Agreement State to perform bioassays for I-125.

Thyroid bioassay action levels and actions are set at the levels described in paragraph 5 of NRC Regulatory Guide 8.20.

Radiation Surveys

Contamination Surveys

Routine contamination surveys will be performed on a monthly basis where radioactive materials have been used since the last survey. Individuals responsible for each lab area will conduct the survey and maintain records of the survey. The Radiation Safety Officer will be responsible for designing a uniform survey method and reviewing survey results. Contamination surveys will be done by swiping surfaces such as bench tops, equipment, floors, refrigerators, freezers, storage cabinets, etc., with swipes (e.g., filter papers or Styrofoam pellets) and assaying the swipes for radioactivity. Removable contamination in excess of 300 dpm per 100 cm2 will be decontaminated promptly by the responsible individual. Removable contamination levels in excess of 3000 dpm per 100 cm2 will be reported promptly to the Radiation Safety Officer and decontaminated. The monthly contamination survey will also incorporate a scan of surfaces using a thin-window Geiger ratemeter. Other than radioisotope work in process and identified storage areas, spots or areas greater than 1000 cpm with the thin-window Geiger survey meter will be marked with radiation warning tape and noted on the survey sheet. Such spots or areas of contamination will be decontaminated promptly by the responsible individual to levels as low as reasonably achievable.

Consideration of Need for Environmental Release Air Sampling Surveys (H-3)

Monitoring or air sampling of airborne release levels from the laboratory hoods is not necessary based the following worst case scenario calculation. None of the radionuclides are in compounds which are particularly volatile. In the case of H-3, for example, the worst case scenario might be release of 1-10 mCi in a laboratory hood over the course of one year. If 10 mCi of H-3 were released in a hood measuring 4 feet wide by 18 inches high and operating at 100 feet per minute (i.e., 600 cfm), the annual average concentration in this hood would be $1x10^{-9}$ uCi/ml. This is only 1% of the H-3 concentration limit of $1x10^{-7}$ uCi/ml for unrestricted areas. (This calculation does not take into consideration the additional dilution from additional non-radioactive exhaust air from other hoods in the ventilation system and from dispersion dilution at the rooftop stack.) Therefore, no hood duct air sampling is required.

Consideration of Need for Environmental Release Air Sampling Surveys (I-125)

All radioiodine will be obtained in pre-labeled form. The licensee will not do labeling of compounds with I-125 at this facility. As such, I-125 will be in a chemical form which is non-volatile. Therefore, air sampling of exhaust air (e.g., hood ducts) will not be necessary.

Release of Individual Laboratory Rooms and Equipment

Individual laboratory rooms and pieces of equipment that had been used for unsealed radioactive material will be released for unrestricted use only after radiological decommissioning. The RSO will be responsible for decommissioning and will decommission or supervise the decommissioning of individual rooms and equipment.

Decommissioning will include radiation survey(s), decontamination and a final radiation survey. Decontamination will consist of cleaning or abrading of surfaces and/or removal of material such as floor tiles, bench tops and equipment as radioactive waste. The radiation survey will consist of careful scanning with the appropriate radiation survey meter. Labs will be divided into grid squares and will include benches, floors, hoods and walls. Each grid square will be evaluated as to fixed contamination, removable contamination and dose rate. Fixed contamination will be evaluated with a portable survey meter slowly scanning at 1 cm from the surface, and expressing the result in dpm/100cm^2. Removable contamination will be evaluated by swiping the surfaces, analyzing by liquid scintillation counting, and expressing the result in units of dpm/100 cm^2. Dose rate will be evaluated by scanning the surfaces with a portable survey meter that has a thin window (not more than 7 mg / cm^2 of total absorber) and reads dose rate directly such as a thin window ion chamber ratemeter.

Labs and equipment will be released for unrestricted use if they meet the criteria in "Guidelines for Decontamination of Facilities and Equipment Prior to release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," US Nuclear Regulatory Commission, May 1987. Alternatively, the RSO may release individual labs or rooms for unrestricted use by applying the criteria of "Radiological Criteria for License Termination," Subpart E, 10 CFR 20 (final

rule as promulgated in Federal Register, 21 July 1997, Page 39058 - 39092). This final rule gives a radiological criteria for release for unrestricted use of 25 mrem Total Effective Dose Equivalent (TEDE) to the average member of the critical group, and that the TEDE is as low as is reasonably achievable. The TEDE to the average member of the critical group will be assessed using the results of the above described radiation survey and a computer model acceptable to the NRC such as the RESRAD-BUILD computer program ("RESRAD-BUILD: A computer Model for Analyzing the Radiological Doses Resulting from the Remediation and Occupancy of Buildings Contaminated with Radioactive Material," Environmental Assessment Division, Argonne National Laboratory, US Department of Energy, November 1994) or other computer code acceptable to the NRC.

Records of decommissioning of rooms will be maintained.

Records Management Program

The Radiation Safety Officer, or his specific designee, will be responsible for maintaining all required records relating to radiation safety and regulatory compliance. Record systems will be established for the following radiation protection related functions:

Incoming radioactive materials received.

Radioactive materials (non-waste) shipped out, if any.

Radioactive waste disposed in sewer, if any.

Radioactive waste decayed, surveyed and disposed as non-radioactive waste.

Radioactive waste shipped to commercial waste broker.

Inventory of radioactive materials on hand.

Personal dosimetry ("film badge") records.

Urine bioassay records, if any

Incident and accident investigations, if any.

Routine contamination surveys.

Records of use areas and spills relating to final decommissioning (as per 10 CFR 30.35(g))

Instructions to Personnel

Persons who work with radioactive materials will receive written radiation safety instructions as follows.

Instructions for All Lab Personnel Using Radioactivity

11. Lab coats must be worn when dispensing or transferring radioactive materials. Other devices such as gloves, remote grippers, radiation shields, pipettors, absorbent paper, and similar equipment are available and must be used whenever appropriate.
12. Never pipette radioactive solutions by mouth.
13. Absolutely no eating, drinking, smoking or storing of food or beverages shall be permitted where radionuclides are in use or in storage. Limited consumption of food and beverages at a desk in a lab may be permitted by the RSO if radioactive materials are prohibited from the desk and limited to specific other areas in the lab.
14. Disposable plastic-backed absorbent sheets or impervious cleanable surfaces (e.g., plastic trays or Teflon coatings) shall be placed on lab benches to contain radioactive solutions if spilled.
15. A hand-held radiation survey meter shall be used during and after all radionuclide operations to follow the progress of the radioactive species during the experiment and to identify contamination.
16. Never put radioactive waste in the ordinary garbage.
17. Notify your supervisor or the Radiation Safety Officer of any spills except those of a very minor nature.
18. Radionuclide work shall be done in a chemical fume hood whenever the possibility exists of airborne contamination because of rapid evaporation, flaking, dusting or aerosolization of the radioactivity.
19. A radiological clean up shall be performed after each major operation or experiment with radioactivity. All lab work areas, lab equipment, glassware, etc. shall be decontaminated to near background levels with the aid of a radiation survey meter. Contaminated equipment in routine radioisotope use may remain contaminated if clearly labeled.
20. Glassware, and similar reusable equipment, shall be thoroughly rinsed twice into the liquid radioactive waste collection container before placing into the normal lab cleaning process.
21. Never store food or beverages in refrigerators or freezers which also contain radioactive materials.
22. Contamination surveys must be performed at least monthly in all active radioisotope use areas. Additionally, each user will use a radiation survey meter to check for contamination and relative radiation levels during each experiment.

23. Every storage container of radioactive materials (including waste, glassware, contaminated equipment, etc.) must be labeled with the standard "Caution Radioactive Material" label with the isotope, the date, and an estimate of the activity. (NRC rules allow for certain exceptions, see Radiation Safety Officer.)

24. Every room or area where radioactive material is used or stored must be posted with the standard "Caution Radioactive Material" sign.

25. If you are issued a whole body radiation dosimeter ("film badge"), wear it clipped to the lab coat, shirt pocket or collar. Dosimeters will be collected by the Radiation Safety Officer or his designate and exchanged for new dosimeters. All persons issued radiation dosimeters are responsible for their proper wearing and routine exchange.

26. Persons must use the principles of radiation protection to reduce their radiation dose to levels which are as low as reasonably achievable (ALARA).

27. Radioactive waste will be collected in the laboratory. Different isotopes should not be mixed in the same waste collection container. Radioisotopes with half lives less than 90 days will be held in the waste storage room for decay for at least 10 half lives. Only the Radiation Safety Officer or his specific designate may authorize the disposal of decayed waste. All waste containers will be labeled with the standard "Caution Radioactive Materials" label and with the isotope, estimated activity in microcuries or millicurie, and the date. Solid and liquid waste will be kept in separate containers. Mixing of materials resulting in a mixture of radioactive and hazardous waste (e.g., heavy metals, organic solvents) is not sanctioned. Radioactive waste may be disposed into the sewer only if it is soluble material or readily dispersible biological material, and only with the prior written authorization of the Radiation Safety Officer.

28. Radiation users are required to know the quantities of radioactive materials in their possession (including waste) and provide this to the Radiation Safety Officer or his specific designate upon demand. Records allowing this information to be generated must be kept by the radiation user. The Radiation Safety Officer will maintain centralized records of the current radioisotope inventory with sufficient accuracy to assure that the total possession of licensed material does not exceed the license limit.

29. Pregnant radiation users may choose to declare their pregnancy with the Radiation Safety Officer. (Declaring your pregnancy is **not** mandatory.) For declared pregnant radiation users, the company will take steps to keep the radiation dose to the embryo/fetus to approximately 10% of that allowed for adult radiation workers. See Radiation Safety Officer for more information.

Special Rules for Using More Than 1 mCi of P-32

1. Scan for radioactive contamination after each use, or at least daily if use is continuous, using a thin window Geiger-type radiation survey meter.

2. Use impervious gloves and eye protection such as safety glasses or goggles.
3. Wear a ring dosimeter under the glove in addition to the required body badge dosimeter.
4. Conduct a "dry run" prior to performing any unfamiliar procedure in order to preclude unexpected complications. The "dry run" will be done with zero or trace levels of activity. The Radiation Safety Officer will observe and/or supervise the first "hot run" of any unfamiliar procedure.
5. Use 1/4-inch thick clear plastic (e.g., Plexiglass®) bench shields, container shields and vial shields as appropriate.
6. If skin or clothing become contaminated, take immediate action as prescribed in the emergency procedures.

Special Rules for Using More Than 1 mCi of I-125

1. Scan for radioactive contamination after each use, or at least daily if use is continuous, using a sodium iodide crystal detector probe type radiation survey meter.
2. Notify the Radiation Safety Officer when planning experiments which will use > 1 mCi of I-125. RSO will determine if thyroid bioassays are necessary.
3. Keep waste solutions at a basic pH to minimize the volatility of iodine.
4. Conduct a "dry run" prior to performing any unfamiliar procedure in order to preclude unexpected complications. The "dry run" will be done with zero or trace levels of activity. The Radiation Safety Officer or designate will observe and/or supervise the first "hot run" of any unfamiliar procedure.
5. Utilize metallic shielding material (e.g., steel, copper, brass, lead, etc.) whenever possible to shield the low energy photon radiation from I-125.
6. Iodine-125 may not be moved from room to room unless it is in a closed container or protected against vaporization into the air.
7. Use impervious gloves and eye protection such as safety glasses or goggles.
8. Wear a ring dosimeter under the glove in addition to the required body badge dosimeter
9. If skin or clothing become contaminated, take immediate action as prescribed in the emergency procedures.

Emergency Procedures

General Guidelines

Even in a well-planned and executed program the possibility exists that incidents will occur. Recognition of this fact requires that suitable emergency procedures be prepared beforehand and be made known to all persons potentially involved. Each user should give consideration to the nature of possible accidents and be familiar with the following procedures.

All emergencies involving fire, explosion, flooding, etc. shall be brought under control promptly by trained personnel. Fire fighting, first aid, etc. take precedence over radiological considerations until the immediate emergency is stabilized. Once the emergency is under control, the Radiation Safety Officer will direct all follow-up operations including radiation monitoring and decontamination. Emergencies involving radioactive material will be handled according to the following emergency procedures.

Missing Material

When radioactive material is suspected of or confirmed to be missing, report the event to the Radiation Safety Officer immediately. The Radiation Safety Officer will conduct an investigation and determine whether NRC must be notified.

Minor Radioactive Material Spills (< 1 mCi)

1. Immediately notify all other persons in the room.
2. Clear the room of all persons except those needed to deal with the spill area.
3. Confine the spill immediately. (Use gloves!)
    a. Liquid spills -- Drop absorbent paper or a spill pillow on spill.
    b. Dry spills -- Dampen thoroughly, taking care not to spread contamination (use water unless a chemical reaction would release air contaminants; if water cannot be used, use mineral oil).
4. Decontaminate.
5. Monitor all persons involved in spill and cleaning.
6. Do not resume work in area until a survey is made showing that the contamination has been removed and the approval of the Radiation Safety Officer is obtained.

Major Radioactive Material Spills (> 1 mCi)

In general, a spill or accident outside of a hood involving more than 1 mCi will require the use of this emergency procedure, whether the material spilled is in dry or wet form.

1. Vacate the room, shutting off equipment if possible. Post a warning sign on the closed door.
2. Enter the room only under the supervision of the Radiation Safety Officer or a designate, and with suitable precautions.
3. Remove clothing suspected of having been contaminated and returned to the room in which the accident occurred or to a closed radioactive waste container (do not transport through the building).
4. If any of the spilled material may have come into contact with the skin, or any part of the individual's body, wash or flush with water and use an emergency shower if necessary.

   The amount of activity on the person before and after washing should be determined, if possible. The amount of material involved in the spill should be ascertained so that this information may be given to the Radiation Safety Officer.
5. As soon as the spill has occurred, assistance should be sought by notification of:
   a. The Radiation Safety Officer
   b. The supervisor under whose supervision the person is working.
6. The Radiation Safety Officer will direct the cleanup and radiological survey to verify the efficacy of the cleanup.

Decontamination of Personnel

When an individual is seriously injured as a result of a laboratory accident, the first consideration should be to seek medical attention.

Decontamination of the skin and clothing should be performed after necessary first aid is administered. Contaminated clothing should be removed. Thorough washing with soap and warm water is the best method for decontamination of the hands and other parts of the body regardless of the contaminant.

Individuals who are cut by glassware or injured by hypodermic needles should wash the affected part under a strong stream of water immediately. Persons swallowing radioactive material should be treated as for poisoning. In cases of ingestion, bioassay samples may be required.

The Radiation Safety Officer will perform a complete incident investigation including an estimate of the skin dose and other administrative and radiological information relating to NRC compliance.

Transportation Requirements

Licensed material transported off site must be done in accordance with hazardous materials transportation regulations, including the rules of the US Department of Transportation, 49 CFR.

If licensed material is transferred to another person or institution, that person or institution's radioactive material license must be verified as to type, form, quantity and shipping destination. Acceptable methods of license verification are found in NRC regulation 10 CFR 30.41.

Material Acquisition

The Radiation Safety Officer will approve all requests to order or otherwise acquire radioactive materials to ensure that the material may be possessed by authority of license and that activity limits will not be exceeded. Each order placed for radioactive material will be logged in the inventory system to maintain inventory control after the order arrives.

Package Receiving Procedures

Incoming packages of radioactive materials will be logged into the appropriate radioactive package log immediately upon receipt at the facility. The log entry will indicate the isotope, the amount in mCi or uCi, the vendor or sender, the name of the person who will use it, the date, and the initials of the person entering the information. Packages of radioactive material will be moved as soon as possible to the authorized laboratory or storage location.

Package Survey for External Contamination

Packages labeled with a Radioactive White I, Radioactive Yellow II or Radioactive Yellow III US DOT label, or packages with evidence of degradation of package integrity (such as crushed, wet or damaged) will be surveyed for **external contamination** within 3 hours of receipt (see NRC regulation 10 CFR 20.1906(b, c, d)).

Incoming packages will be monitored for **external contamination** using the following procedure.

1. Assay the package for surface contamination as soon as possible, but no later than 3 hours after its arrival at the building. (If received during non-business hours, it must be assayed within 3 hours from the start of the next business day.)
2. Put on disposable impervious gloves and a lab coat.
3. Place the package in a secure place in the lab.
4. With a swipe (e.g., filter paper or Styrofoam pellet), swipe all sides of the outer package, covering about 300 cm^2 or more.

5. Assay the swipe for net radioactivity (in dpm or microcuries, but not cpm) using the liquid scintillation counter. If more than one swipe per package is taken, the one with the highest radioactivity will determine the contamination level.
6. If the net radioactivity on the outside of the package is greater than 6600 dpm, immediately take the following action:

    a. Notify the Radiation Safety Officer.
    b. Notify the final delivering carrier.
    c. By telephone and telegraph, mailgram or facsimile, notify the U.S. Nuclear Regulatory Commission Region I Office, 475 Allendale Road, King of Prussia, PA.

        Phone: 610-337-5000
        Fax: 610-337-5393/5368/5234/5269

7. If the net radioactivity on the outside of the package is greater than 660 dpm, take the following action:

    a. Notify the Radiation Safety Officer or the authorized Principal Radiation User of the contamination.
    b. Place a label on the package giving the contamination level.
    c. Keep the package on a disposable absorbent pad or impervious plastic sheet.
    d. Wearing gloves and a lab coat, open the package in a laboratory hood, monitoring contamination levels with a suitable radiation survey meter.
    e. Dispose of contaminated packaging material as radioactive waste.
    f. If the inner container is broken or leaking, transfer any remaining radioactive material to a new container, seal shut, and apply the appropriate label and label information.

Package Survey for Radiation Level

Incoming packages must be monitored for **radiation level** as part of the receiving procedure only if there is evidence of package degradation such as a package that is crushed, wet or damaged. The radiation level survey must be completed within 3 hours of receipt.

1. Measure the external radiation level, in mR/h, on the package surface and at a distance of one meter from the surface.
2. Record the results.
3. If measured levels exceed 200 mR/h at any point on the surface, or if the measured levels at any point at one meter from the surface exceeds 10 mR/h, immediately take the following action:
    a. Notify the Radiation Safety Officer.
    b. Notify the final delivering carrier.

c. By telephone and telegraph, mailgram or facsimile, notify the U.S. Nuclear Regulatory Commission Region I Office, 475 Allendale Road, King of Prussia, PA.

Phone: 610-337-5000
Fax: 610-337-5393/5368/5234/5269

Package Opening Procedures

The following procedure will be used for opening all radioactive packages received at the licensee:

1. If the package appears to be damaged (such as wet, crushed or leaking) notify the Radiation Safety Officer immediately. The Radiation Safety Officer will measure the external dose rate and direct the opening of the package.
2. Keep the package on a disposable absorbent pad, impervious plastic sheet, or non-porous cleanable surface.
3. Wearing gloves and a lab coat, open the package, monitoring contamination levels on packaging materials and container surfaces with a suitable radiation survey meter.
4. Dispose of any contaminated packaging material as radioactive waste.
5. If the inner container is broken or leaking, transfer any remaining radioactive material to a new container, seal shut, and apply the appropriate label and label information.
6. Store the radioactive material in a secure and posted location. If the radionuclide is a high energy beta or a gamma emitter, use sufficient shielding so that the ambient dose rate to any major portion of the human body is below 2 mrem per hour.

Radiation Safety Training

Training for Radiation Users

Radiation safety training (Basic Radiation Safety) will be provided to Principal Radiation Users and to workers who use radioactive materials under the supervision of a Principal Radiation User. There will be periodic re-training (Radiation Safety Refresher) of these workers on an annual basis. The Radiation Safety Officer shall keep records of all radiation safety training.

The initial Basic Radiation Safety training session will consist of a 2 to 4 hour didactic presentation which will cover the following topics:

1. Naturally Occurring Population Radiation Exposures

2. Anthropogenic (Man-made) Population Radiation Exposures
3. Physical Properties of Ionizing Radiations
4. Radiological Units of Measure
5. Biological Effects of Radiation
6. Radiation Protection Standards for Employees
7. As Low As Reasonably Achievable (ALARA) Concept
8. Radiation Protection Instrumentation
9. Personnel Dosimetry - Assessment of External and Internal Dose
10. Radiation Shielding
11. Contamination Control
12. Radioisotope Laboratory Safety Rules
13. Emergency Procedures

Training for Ancillary Personnel

Ancillary personnel (clerical, administrative, management, housekeeping, security, etc.) whose duties may require them to work in the vicinity of radioactive material will be informed about radiation hazards and appropriate precautions they may need to take. The Radiation Safety Officer will provide for the necessary instruction to such personnel initially and annually thereafter on a refresher basis. The initial instruction will be given by or under the direction of the Radiation Safety Officer and will consist of approximately 15 minutes of instruction and 15 minutes of questions and answers. The instruction will include the following topics: NRC's role in licensing, regulation and inspection; signs and labels; radiation and radioactivity; keeping exposures as low as reasonably achievable; laboratory safety rules; and emergency instructions.

Audits of Radiation Safety Program Content and Implementation

At least once per year, management will arrange for an audit of the content and implementation of the radiation safety program. The audit will include a walk-through survey covering areas where people store or use radioactive material. Additionally, it will include a review of required records such as records of personnel dosimetry, internal dose assessment (bioassay), incident investigations, radioisotope inventory, radioisotope receipt surveys, contamination surveys, environmental release surveys, radioactive material shipments, radiation safety training and security. The annual audit will be conducted by a health physicist certified by the American Board of Health Physics, and the audit report will be presented to company senior management.

Quarterly, the RSO will conduct an audit of the use of radioactive material within the company. This quarterly audit will include a review of routine contamination surveys, lab techniques and practices, storage of radioactive materials, general housekeeping, proper signs and labels, and security.

Question 11 - Waste Management

Waste will be managed by one of the following four methods: decay for at least 10 half-lives and disposal as non-radioactive waste; transfer to a licensed radioactive waste broker for further management and/or disposal as radioactive waste; dispose of certain liquid scintillation solution as non-radioactive waste; and disposal into the sanitary sewer system serving the laboratory facility.

Storage for Decay

Radioactive waste with half-lives less than 90 days may be held for at least 10 half-lives, and disposed as non-radioactive waste. All waste destined for decay will be labeled with the standard radiation caution label, the isotope, the approximate activity, and the date. It will be held in the laboratory or the radioactive waste storage room for decay. Following the prescribed decay period, the material will be surveyed with an appropriate survey meter for any detectable external radiation levels. The waste will be disposed as non-radioactive waste only if the survey shows that the waste cannot be distinguished from background. Prior to disposal as non-radioactive waste, all labels and references to radioactivity will be removed or obliterated.

For each package of radioactive waste, a record will be kept of the process including date of disposal, date on which the byproduct material was placed into storage, the radionuclide(s) disposed, the survey instrument used, the background meter reading, the radiation level measured at the surface of each waste container and the name of the individual who performed the disposal.

Transfer to Commercial Radioactive Waste Broker or Processor

Radioactive waste with half-lives longer than 65 days will be packaged in 30 or 55 gallon drums supplied by the radioactive waste disposal broker or processor. A radioactive waste broker or processor licensed by the NRC or an Agreement State will be used. The brokers under consideration for contract waste removal are Teledyne Brown Engineering Environmental Services of Westwood, NJ, and Radiac Research Corp. of Brooklyn, NY. A log of cumulative activity by isotope will be placed at each drum so that the total activities of each isotope can be determined. No liquids will be allowed in these drums. Liquid radioactive waste requiring solidification prior to shipment will be solidified using an approved solidification method.

Certain Spent Liquid Scintillation Solution

Spent liquid scintillation solution containing only H-3 and/or C-14 and with a concentration of less than 0.05 uCi/ml may be disposed as if it were not radioactive. Records of such disposals will be maintained.

Disposal to the Sewer

Liquid radioactive waste may be disposed of in a sink or drain leading to the sewer if it is readily soluble material or readily dispersible biological material. This procedure will be within the regulations of 10 CFR 20.2003 as demonstrated by the following sample calculations.

The sewer flow rate from the facility is estimated at a nominal 2,000 gallons per month. Using this sewer flow rate and the sewer disposal limits specified in 10 CFR 20.2003(a), the limits for allowable quantities which may be disposed of into the sewer per month are calculated as follows:

Sample Calculation of Monthly Sewer Release Limits for a Particular Sewer Flow Rate		
Radionuclide	Monthly Sewer Concentration Limit Table 3, (Appendix B, 20.1001-2401)	Calculated Monthly Sewer Release Limit
	uCi/ml	mCi/month
Hydrogen-3	1.00e-02	75.8
Carbon-14	3.00e-04	2.3
Phosphorus-32	9.00e-05	0.7
Phosphorus-33	8.00e-04	6.1
Sulfur-35	1.00e-03	7.6
Calcium-45	2.00e-04	1.5
Iodine-125	2.00e-05	0.2

The above table shows release limits if a single radionuclide only is released into the sewer. A sum of ratios method will be applied if more than one radionuclide is released. Also, total activity disposed to the sewer per calendar year will be limited to 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined.

The above sample calculation illustrates that the sewer can be used as a disposal method where releases would be within the limits of 10 CFR 20.2003. Actual sewerage flow will be determined from water meter readings or other available means. Activity of each radionuclide in each container will be determined and recorded prior to disposal in the sewer. Actual average sewer concentrations will be calculated monthly when disposal occurs during that month. Liquid waste disposal into the sewer drain will be under the direct control of the Radiation Safety Officer who will authorize such disposal. The Radiation Safety Officer will keep records of all radioactive materials disposed into the sewer.

Attachments

Radiological Training and Experience Summaries of Authorized Radiation Users

Resume of David A. Elsemore, PhD, Radiation Safety Officer

Figure 1 - Floor Plan Showing Radioisotope Areas

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: John Cantello, PhD **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Univ. of Delaware, Newark, DE	1992, 6 hrs	Radiation Safety user training.
Univ. of Delaware, Newark, DE	1993, 6 hrs	Radiation Safety user training.
Univ. of Delaware, Newark, DE	1994, 6 hrs	Radiation Safety user training.
Univ. of Delaware, Newark, DE	1995, 6 hrs	Radiation Safety user training.
California Pacific Medical Ctr, San Francisco, CA	June 1996, 2 hrs	Radiation Safety

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Univ. of Delaware, Newark, DE	1992-1996	P-32 S-35	0.2 mCi 0.01 mCi	DNA, RNA labeling DNA sequencing

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: David A. Elsemore, PhD **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Yale University, New Haven, CT	1993, 3 hrs	Radiation Safety. Basic training on isotope ue and handling.
Dupont Co., Wilmington, DE	1995, 1 hr	Radiation Safety. Basic training and compliance.
Dupont Co., Wilmington, DE	1996, 1 hr	Radiation Safety. Basic training and compliance.
Dupont Co., Wilmington, DE	1997, 1 hr	Radiation Safety. Basic training and compliance.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Yale University, New Haven, CT	1989-1995	P-32	0.1 mCi	Sequencing, blotting, and labeling.
Yale University, New Haven, CT	1989-1995	S-35	0.1 mCi	Sequencing, blotting, and labeling.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Weihong Hsing **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
University of Mass., Amherst, MA	1992, 4 hrs	Principles of radioisotopes, Radiation Safety lecture.
Princeton University, Princeton, NJ	1993, 1-3 hrs	Radiation Safety training.
Princeton University, Princeton, NJ	1994, 1-3 hrs	Radiation Safety training.
Princeton University, Princeton, NJ	1995, 1-3 hrs	Radiation Safety training.
Princeton University, Princeton, NJ	1996, 1-3 hrs	Radiation Safety training.
Princeton University, Princeton, NJ	1997, 1-3 hrs	Radiation Safety training.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
University of Mass., Amherst, MA	1992-93	H-3	0.01 mCi	
Princeton University, Princeton, NJ	1994-97	H-3 P-33 C-14 S-35 P-32	0.002 mCi 0.1 mCi 0.002 mCi 0.1 mCi 0.1 mCi	UV cross linking of nucleotide, DNA sequencing, in vitro kinase phosphatase assay.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Vladimir Khazak **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
VNII Genetica, Moscow, Russia	1986, 4 hrs	Radiation safety lecture
Fox Chase Cancer Center, Philadelphia, PA	1996, 4 hrs	Radiation safety course and test.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
VNII Genetica, Moscow, Russia	1986-93	P-32 P-33 S-35	1.0 mCi 1.0 mCi 1.0 mCi	Sequence analysis, southern blots.
Fox Chase Cancer Center, Philadelphia, PA	1993-1997	P-32 S-35	1.0 mCi 5.0 mCi	Sequence, Northern blots, Southern blots, in vivo labeling of yeast.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Krishna Kodukula, PhD **Title:** Executive Director

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Roche Institute of Molecular Biology, Nutley, NJ	1989-1993, 2-3 hrs each	Initial and yearly refresher course on radiation usage and disposal given by the RSO of Hoffmann La Roche Inc., Nutley, NJ.
Bristol Myers Squibb Pharmaceutical Research Institute, Wallingford, CT	1993-1997, ~2 hrs each	Initial and yearly refresher course on radiation usage and disposal offered by the RSO of BMSPRI, Wallingford, CT

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Roche Institute of Molecular Biology, Nutley, NJ	1989-1993	S-35 P-32 P-33 H-3 C-14	several microcuries per experiment	protein purification, enzyme kinetics, metabolic labeling, DNA sequencing.
Bristol Myers Squibb Pharmaceutical Research Institute, Wallingford, CT	1993-97	S-35 P-32 P-33 H-3 C-14 I-125	several microcuries per experiment	radioligand binding, receptor labeling and purification, protein purification and labeling, enzyme labeling and kinetics.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Wei Liu **Title:** Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Duke Univ., Durham, NC	1996, 3 hrs	Principles of radioisotopes. Radiation safety by Duke Univ. medical center. Basic Radiation Protection Principles.
Univ. of North Carolina at Chapel Hill, Chapel Hill, NC	1993, 3 hrs	Short course on radiation safety in research and the utilization of radiation protection and detection.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Duke Univ., Durham, NC	1996-97	C-14 S-35 Cr-51 P-32	0.1 mCi 0.1 mCi 0.1 mCi 0.1 mCi	Southern and Northern blots, sequence in situ.
Univ. of North Carolina at Chapel Hill, Chapel Hill, NC	1993-95	C-14 H-3	0.1 mCi 0.1 mCi	functional and binding assay of protein.
Univ. of North Carolina at Chapel Hill, Chapel Hill, NC	1993-95	I-125	2 mCi	Iodination of calmolutin for binding and overlay studies.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Yi Liu **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Rutgers University, Piscataway, NY	1990, 3 hrs	Radiation safety training
Princeton University, Princeton, NJ	1994, 3 hrs. 1996, 3 hours	Radiation safety training Radiation safety training

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Rutgers University, Piscataway, NJ	1990, 8 months	S-35 P-32	0.1 mCi 0.1 mCi	DNA sequencing labeling nucleic acid
Princeton University Princeton, NJ	1994 - 96	P-32 I-125	0.1 mCi 0.001 mCi	Measure kinase activity Western blot

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Rolf Menzel **Title:** Executive Vice President

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
National Institutes of Health, Bethesda, MD	12/84, 1 week	General Radiation Safety
E.I. DuPont, Wilmington, DE	6/85 - 6/90, annual course, 4 hrs each	Reviews of Radiation Safety
Bristol Myers Squibb, Princeton, NJ	6/90-1997, annual course, 1 hr each	Review of Radiation Safety

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Gulf, San Diego, CA	6/96-6/73, 3 mo/summer	Cs-137, radioiodines, fission prod.	10-1000 mCi	Nuclear fuel quality control
Univ. California, Berkley, CA	6/73-6/79	P-32 C-14 H-3	≤1 mCi ≤1 mCi ≤1 mCi	biology radioisotope experiments
Univ Utah, Salt Lake City, UT	6/79-6/81	P-32 C-14 H-3	≤1 mCi ≤1 mCi ≤1 mCi	biology radioisotope experiments
National Institutes of Health, Bethesda, MD	6/81-6/85	P-32 C-14 H-3	≤1 mCi ≤1 mCi ≤1 mCi	biology radioisotope experiments
E.I. DuPont, Wilmington, DE	6/85-6/90	P-32 C-14 H-3	≤1 mCi ≤1 mCi ≤1 mCi	biology radioisotope experiments
Bristol Myers Squibb, Princeton, NJ	6/90-6/97	P-32 C-14 H-3	≤1 mCi ≤1 mCi ≤1 mCi	biology radioisotope experiments

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Jian Pang **Title:** Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
University of Pennsylvania, Philadelphia	1991, 3 hrs 1993, 3 hrs	Radiation safety lecture by U. Penn. Basic radiation protection principles and safety rules.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
University of Pennsylvania, Department of Pathology, Philadelphia	1991-1993	P-32 P-33	5 mCi 5 mCi	DNA sequencing, Southern blots, screening library.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: James Pei **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Univ. of Pittsburgh, Pittsburgh, PA	4/94, 3 hrs	Radiation safety course on how to handle radioactive materials.
Univ. of Pennsylvania, Philadelphia, PA	7/96, 3 hrs	Radiation safety course on how to handle radioactive materials.
Univ. of Pennsylvania, Philadelphia, PA	7/97, 3 hrs	Radiation safety course on how to handle radioactive materials.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Univ. of Pittsburgh, Pittsburgh, PA	1994-1996	P-32 H-3	0.1 mCi 0.1 mCi	Cell labeling and enzyme assays.
Univ. of Pennsylvania, Philadelphia, PA	1996-1997	P-32 H-3	0.1 mCi 0.1 mCi	Cell labeling and enzyme assays.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Patrick Romano **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Miami University, Oxford, OH	1983, two 3 hr sessions	Radiation safety: testing and certification to work with radioisotopes.
National Institutes of Health, Bethesda, MD	July 1992 1993 1995	Formal 3 hr course with testing. Yearly refresher course (1 hour) with testing.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Miami University, Oxford, OH	1983-85	P-32	µCi	DNA labeling
Harvard, University, Boston, MA	1986-87	P-32 H-3	µCi	Nucleotide labeling, Cell labeling
Wesleyan University, Middletown, CT	1987-91	P-32 S-35	µCi - mCi	Nucleotide and protein labeling
National Institutes of Health, Bethesda, MD	1992-97	P-32 S-35	µCi - mCi	In vivo protein labeling, nucleotide labeling

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Hai Sheng **Title:** Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Jefferson University	1990, one semester	Principles of Radioisotopes
University of Pennsylvania	1994	Radiation safety lecture.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Jefferson University	1990	P-32 S-35	1 mCi 1 mCi	Southern and Western blotting
University of Pennsylvania	1994	P-32	0.5 mCi	Southern blotting and Polymerase Chain Reaction (PCR).

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Jenny Wang **Title:** Senior Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
duPont, Wilmington, DE	1996-1997 annual meetings, 1 hr each	Radiation Safety - basic training and compliance.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Duke University, Durham, NC	1993-1995	I-125 H-3 P-32 P-33 S-35	0.1 mCi 0.1 mCi 0.1 mCi 0.1 mCi 0.1 mCi	ligand binding, labeling, DNA sequencing
Arizona State University	1989-1993	S-35 P-32	0.1 mCi 0.1 mCi	Southern blot, DNA sequencing

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Alicia Warren **Title:** Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Allegheny University - Medical College of PA	Summer 1994, 1 day	General Radiation Safety: Protection, usage, monitoring
Quality Biotech	July 1996	General Radiation Safety: Protection, usage, monitoring
University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, NJ	Summer 1993, 1 hr	General Radiation Safety

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Allegheny University - Medical College of PA	1994-1996	S-35	0.1 mCi	DNA sequencing
Quality Biotech	1996-1997	P-32	0.1 - 5 mCi	DNA sequencing, labeling, hybridizations, blots.
University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, NJ	July-Aug 1993	S-35	0.1 mCi	DNA sequencing

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Weiren Zhang **Title:** Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Thomas Jefferson University	Aug 1992, 4 hrs (lecture and video)	Principles of radioisotopes. Radiation safety and Jefferson rules.
Harvard Medical School	March 1989, 4 hrs lecture	Principles of radioisotopes. Radiation safety

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Thomas Jefferson University	1992-1998	P-32 I-125 S-35 H-3	≤ 0.1 mCi ≤ 0.1 mCi ≤ 0.1 mCi ≤ 0.1 mCi	DNA labeling, Western blots, insulin binding, sequencing of DNA, DNA incorporation in vivo.
Harvard Medical School	1989-1992	P-32 S-35	0.1 mCi 0.1 mCi	DNA labeling and sequencing.

STATEMENT of TRAINING and EXPERIENCE FORM

(For Authorized Radiation User named on NRC License)

Name: Meg Zinda **Title:** Associate Scientist

Formal Courses on Radiation Safety and Radioisotope Technology:

Please list all educational and training courses which included principles and practices of radiation protection, radioactivity measurements, radiation monitoring techniques, and/or biological effects of radiation. (Include college courses, radiation safety training lectures, and short courses.)

Institution, City	Date and duration	Name of course and short description
Vanderbilt University, Nashville, TN	1996-1997, 5 hrs	Radiation safety course, including test and certification upon passing the test.

Experience with radiation:

Please list all the different types of work you have done with radioisotopes or radiation

Institution, City	Date and duration	Radio-isotope(s)	Amount per experiment (mCi)	Type(s) of experiment or use
Vanderbilt University, Nashville, TN	1996-1997	P-32 S-35	0.1 mCi	Sequencing, DNA library screening

Resume of David A. Elsemore, PhD, Radiation Safety Officer

David A. Elsemore

Small Molecule Therapeutics, Inc.
11 Deer Park Dr. Suite 116
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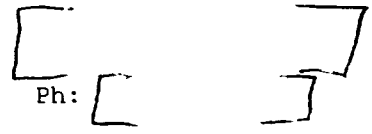
E-mail: elsemore@smtherapeutics.com



Education

Yale University; New Haven, CT 06511
M. S., M. Phil., 1991. Ph.D., 1995

Skidmore College; Saratoga Springs, NY 12866
B. A. in Biology, 1989

Research Experience

1997-present Senior Scientist. Small Molecule Therapeutics Inc.

1995-1997 Development of biosensors responsive to environmental stresses. Herbicide target discovery. Visiting Research Scientist, Central Research and Development; DuPont Experimental Station, Wilmington, DE. Stress-responsive promoters that respond to DNA or protein damage were fused to the bacterial luciferase operon (*luxCDABE*). Reporters were genetically engineered into the *E. coli* chromosome. A second project involves using *E. coli* as a model for herbicide target discovery in central metabolism. **Advisor: Dr. Robert A. LaRossa**

1989-1994 Dissertation Title: Organization, Characterization and Function of the Quinate pathway genes in *Acinetobacter calcoaceticus*. Department of Biology; Yale University; Ph.D. 1995. I have cloned and characterized the *qui* genes, the structural genes for the quinate pathway. Studies included regulation and evolutionary history of the *qui* genes. **Ph.D. advisor: Dr. L. N. Ornston**

1988-1989 Characterization of the Cell Wall Gylcoproteins in Chlamydomonad Flagellates. Department of Biology; Skidmore College, Saratoga Springs, NY Senior Project.
Advisor: Dr. David Domozych

Technical Experience

Genetics: transformation, natural transformation, construction of chromosomal deletions and insertions, complementation, gene fusion, transduction, conjugation, regulation of gene expression

Microbial Physiology: growth curves, regulation studies with *lacZ* fusions, protein overexpression, expression of stress genes with bioluminescent reporters

Biochemistry: preparation of cell lysates and sonicates, enzyme assays, colorimetric assays, protein determination, protein electrophoresis, analytical detection of small molecules

Microbiology: strain maintenance, culture growth, replica plating, cell harvesting, mutant selection

Molecular Biology: DNA restriction enzyme analysis, DNA preparation, DNA cloning, sequencing, labeling of probes, Southern blots, RNA preparation, Northern blots, primer extension, PCR

Professional Appointments and Honors

1994	Enders Research Grant Award, Yale University
1989-1994	Teaching Assistantship; Yale University Course Responsibilities: Introductory Biology, laboratory and course; Genetics laboratory
1989-1993	National Research Service Award
1995	DuPont : "Way to Go" award

Abstracts

Domozych, D. S. and D. A. Elsemore. 1988. The endomembrane system and membrane traffic in the unicellular volvocalean flagellate, *Gloeomonas*. Abstr., 4th International Cell Biology Symposium.

Elsemore, D. A., and L. N. Ornston. 1992. Genes for quinate and shikimate catabolism are part of a supraoperonic cluster in the *Acinetobacter calcoaceticus* chromosome. Abstr., 92nd American Society for Microbiology, p. 220.

Elsemore, D. A. and L. N. Ornston. 1993. Location and DNA sequences of *quiA* structural gene for quinate dehydrogenase in *Acinetobacter calcoaceticus*. Abstr., 93rd American Society for Microbiology, p.192.

Elsemore, D. A. and L. N. Ornston. 1994. Organization of the quinate gene cluster in *Acinetobacter calcoaceticus*. Abstr., 94th American Society for Microbiology, p.114.

Elsemore, D. A. and R. A. LaRossa. 1996. Construction, kinetics and sensitivity of chromosomally located, bioluminescent reporters responsive to DNA or protein damage in *Escherichia coli*. Abstr., 96th American Society for Microbiology, p. 548.

Smulski, D. R., T. K. Van Dyk, D. A. Elsemore, H. Purohit, A. C. Vollmer, and R. A. LaRossa. 1996. Nutritionally-regulated, luxCDABE-based Escherichia coli sensors. Abstr., 96th American Society for Microbiology, p. 509.

Publications

Averhoff, B., L. Gregg-Jolly, D. Elsemore and L. N. Ornston. 1992. Genetic analysis of supraoperonic clustering by use of natural transformation in *Acinetobacter calcoaceticus*. Journal of Bacteriology **174** (1): 200-204.

Elsemore, D. A. and L. N.Ornston. 1994. The *pca-pob* supraoperonic cluster of *Acinetobacter calcoaceticus* contains *quiA*, the structural gene for quinate/shikimate dehydrogenase. J. Bacteriol. **176**:7659-7666.

Elsemore, D. A. and L. N. Ornston. 1995. Unusual ancestry of dehydratases associated with quinate catabolism in *Acinetobacter calcoaceticus*. J. Bacteriol. **177**:5971-5978.

Kloos, D., A. A. DiMarco, D. A. Elsemore, K. N. Timmis and L. N. Ornston. 1995. Distance between alleles as a determinant of linkage in natural transformation of *Acinetobacter calcoaceticus*. J. Bacteriol. **177**:6015-6017.

Elsemore, D. A. 1995. Organization and characterization of genes for quinate degradation in *Acinetobacter calcoaceticus*. Ph.D. thesis, Yale University.

Figure 1 - Floor Plan Showing Radioisotope Areas