NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

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

Licensee	
1. Kimeragen, Inc.	3. License Number 37-30363-01
2. 300 Pheasant Run Newtown, Pennsylvania 18940	4. Expiration Date February 28, 2002
	5. Docket or Reference No. 030-34323

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen 3	A. Any	A. 20 millicuries
B. Carbon 14	B. Any	B. 10 millicuries
C. Phosphorous 32	C. Any	C. 20 millicuries
D. Phosphorous 33	D. Any	D. 20 millicuries
E. Sulfur 35	E. Any	E. 20 millicuries
F. Iodine 125	F. Pre-labeled nonvolatile compound	F. 10 millicuries

9. Authorized use

A. through F. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 300 Pheasant Run, Newtown, Pennsylvania.

11. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.

In accordance with the requirements set forth in 10 CFR 30.36(b), 40.42(b), and 70.38(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 37-30363-01
Docket or Reference Number: 030-34323

12. A. Licensed material shall be used by, or under the supervision of, Ramesh Kumar, Ph.D. Licensed material listed in Subitem 6.A. through Subitem 6.E. may be used by, or under the supervision of Patricia Avissar or Maryann C. Gruda, Ph.D.

    B. The Radiation Safety Officer for this license is Ramesh Kumar, Ph.D.

13. Licensed material shall not be used in or on human beings.

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 65 days for decay-in-storage before disposal in ordinary trash, provided:

    A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. Radioactive waste generated under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's application dated January 3, 1997 and letter dated February 11, 1997.

License Number
37-30363-01

Docket or Reference Number
030-34323

MATERIALS LICENSE
SUPPLEMENTARY SHEET

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated January 3, 1997
B. Letter dated February 11, 1997

Date FEB 24 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By
Richard Gibson

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

FEB 24 1997

License No. 37-30363-01
Docket No. 030-34323
Control No. 124076

Jennifer Kmiec
Vice President, Administration
Kimeragen, Inc.
300 Pheasant Run
Newtown, PA 18940

Dear Ms. Kmiec:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

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

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name

OFFICIAL RECORD COPY ML 10

FEB 24 1997

License No. 37-30363-01
Docket No. 030-34323
Control No. 124076

Jennifer Kmiec
Vice President, Administration
Kimeragen, Inc.
300 Pheasant Run
Newtown, PA 18940

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2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   a. when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name

change; or

b. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

a. when you decide to terminate all activities involving materials authorized under the license; or

b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

5. Request and obtain a license amendment before you:

a. permit anyone to work as an authorized user under the license;

b. change Radiation Safety Officer;

c. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

d. add or change the areas of use, or address or addresses of use identified in the license application or on the license; or

e. change ownership of your organization.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

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

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your

license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

Original Signed By
Richard Gibson

Richard Gibson, Jr.
Division of Nuclear Materials Safety

License No. 37-30363-01
Docket No. 030-34323
Control No. 124076

Enclosures:
1. License No. 37-30363-01
2. NRC Form 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L3730363.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	RGibson/rxg							
DATE	02/14/97		02/ /97		02/ /97		02/ /97	

OFFICIAL RECORD COPY

KIMERAGEN, INC.
Molecular Pharmaceuticals

Jennifer L. Kmiec
Vice President, Administration

M516
J-2

February 11, 1997

Richard Gibson, Jr.
Division of Nuclear Materials Safety
US NRC
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Docket No. 030-34323
Control No. 124076

Dear Mr. Gibson:

The following is in response to your letter dated January 16, 1997. Please find following responses to Item #1 and Items #3-13 on separate sheets.

With respect to Item #2, Kimeragen, Inc. would like to have Patricia Avissar and Maryann C. Gruda, Ph.D. listed as Principle Radiation Users for all radioisotopes except Iodine 125. Any use of Iodine 125 shall be under the training and supervision of Ramesh Kumar, Ph.D. and RSO. We hope that this condition is acceptable.

If you have further questions or comments, please contact me or Dr. Kumar at 215-504-4444.

Sincerely,

Jennifer L. Kmiec

Jennifer L. Kmiec
Vice President of Administration

Attachments

DOL 10

124076

FEB 12 1997

300 Pheasant Run Newtown, PA 18940 215-504-4444 Fax 215-504-4545

ITEM #1

Radiation Safety Officer Responsibilities

1. Asses radiological hazards, and prescribe and confirm the implementation of appropriate radiation safety precautions.
2. Verify that the use of licensed material is by or under the direct supervision of Principal Radiation Users specifically listed in the license.
3. Provide initial and annual radiation safety training.
4. Verify, through training and observation, that all users (where appropriate) wear personnel monitoring equipment when using licensed materials and that dose reports are reviewed and evaluated.
5. Ensure, through training and observation, that licensed materials are properly secured against unauthorized removal when not in use.
6. Do routine inspections of all laboratories using or storing licensed materials.
7. Ensure that the terms and conditions of the license are understood and met.
8. Maintain all required records.

The above statement is taken from page 5 of Kimeragen's Radiation Safety Manual, September 1996.

ITEM #3

WRITTEN STATEMENT OF DELEGATION OF AUTHORITY TO KIMERAGEN'S RADIATION SAFETY OFFICER

The Senior Management of Kimeragen Inc. understands the importance of and is dedicated to the strict enforcement of radiation safety in the research laboratory. The position of Radiation Safety Officer will be filled by an experienced scientific staff member who possesses appropriate training and has demonstrated an understanding of the safety issues surrounding the use of radiation in the laboratory.

Based upon the acknowledged need of strict supervision, it is the intention of Senior Management at Kimeragen, Inc. to give to this position sufficient authority to communicate and direct the Radiation Safety Program. In so doing, it is acknowledged that the Radiation Safety Officer shall have the authority to:

a. Communicate with personnel regarding NRC regulations and Kimeragen's license provisions;
b. Enforce the Kimeragen Radiation Safety Program and all NRC regulation;
c. Terminate any unsafe operation including any operations that the RSO believes may be unsafe until the RSO is satisfied that said operation conforms to NRC regulations;
d. Seek amendments to the license as may be necessary from time to time; and
e. Report to Senior Management annually regarding the status of the licensed program.

It is the policy of Kimeragen, Inc. to provide laboratory and office workers with a safe work environment and this delegation of authority is given to enhance that policy. For purposes of radiation safety, the RSO will communicate regarding the program with the President and Vice President of Administration.

ITEM #4

Annual Radiation Safety Program Audit:

Kimeragen, Inc. Management, in cooperation with its Radiation Safety Officer, will arrange for an annual audit of the content and implementation of the radiation safety program. The audit will be conducted by an independent radiation safety professional who will furnish a written audit report to management. (page 31, Kimeragen's Radiation Safety Manual, Sept. 96).

This audit will include a presentation to Senior Management regarding the NRC regulations, the provisions of the license and the compliance status of Kimeragen's licensed program. The audit will also include a review of the RSO and staff's performances. The independent radiation safety professional will be a Ph.D. with a minimum of 10 years experience in radiation safety (presently, Wesley R. Van Pelt, Ph.D. of Paramus, NJ consults in this capacity).

As part of the Radiation Safety Program at Kimeragen there shall be annual audits internally including review of users' inventory and survey records, evaluation of users' radiation safety procedures through observation and discussion, and performance of independent work area surveys.

ITEM #5

Kimeragen, Inc. is presently residing in 5000 square feet of office and laboratory space. The laboratory is designated as the only location for use of licensed materials. A map of the laboratory is marked and attached hereto.

Packages will be delivered to the laboratory and placed in the Radiation Receiving area (marked A on the map) in a plastic lipped radiation tray (Scott Labs bench protector) until the user receives the materials. If not for immediate use, the radioisotope will be stored in the appropriate locked freezer, marked with its isotope, the amount and the date of receipt and end user. Appropriate shielding for $^{32}P/^{33}P$ and pigs for other isotopes will be used.

In the Radiation Receiving and Primary Use area (A and B on map), Plexiglas shielding shall be mounted on the side and back of the bench. Enclosure of the Radiation Primary Use area is being discussed with appropriate municipal authorities and Kimeragen's Senior Management. Said enclosing would consist of placing a wall and door perpendicular to the scintillation counter. When radioisotope is used on a user's bench, appropriate shielding (Scott Lab shielding) will be used where appropriate.

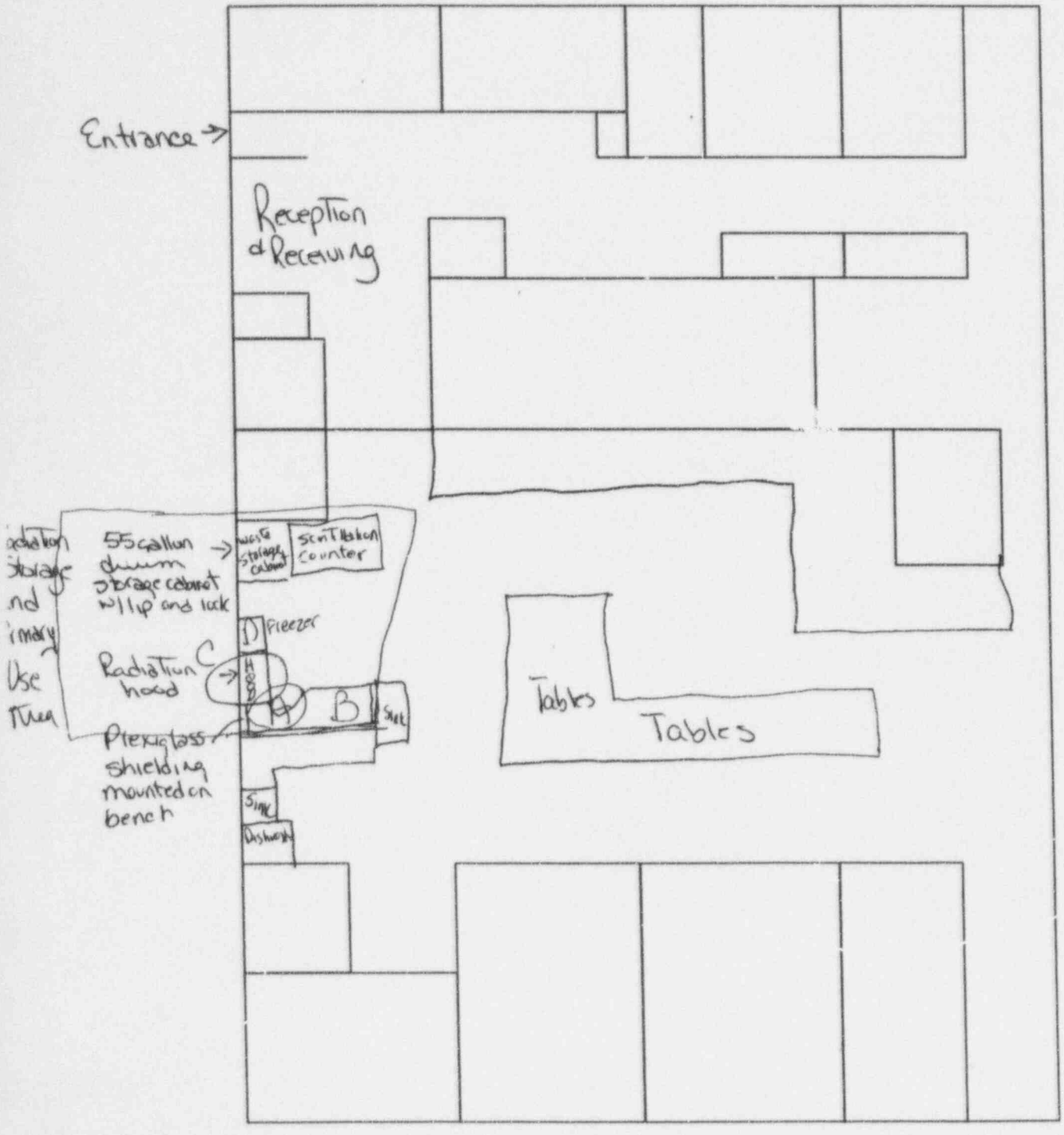
Ludlum Instruments Geiger counters will be used to monitor where appropriate. The Radioisotope hood (C on the map), which vents directly outdoors through appropriate filtration, has been designated for handling the source.

Benches will be marked with tape and covered with bench trays (Scott Lab bench protectors) to contain the radioisotope while in use. An area for common equipment (i.e. micro centrifuges, incubated shaker and hybridizer) has been provided for by the hood (B on the map)

For purposes of pre-labeled I-125 materials, lead shielding will be provided for in the hood and adjacent area.

Space for waste storage cabinet (Eagle brand 55-gallon drum storage cabinet with spill guard) and Wallac scintillation counter have been provided against the far wall in the Radiation Use Area as marked on the map. The floor shall be marked and the storage cabinet shall be locked at all times.

Since all radioisotope will be in liquid form, no danger of material becoming airborne exists.



A: Receipt of materials from FedEx.

B: Isotope use area

C: Isotope hood

D: Radiation Storage Freezer

ITEM #6

Pursuant to and in accordance with 10 CFR 20.1801, Kimeragen maintains a security system on the building and within the laboratory.

Kimeragen, Inc. is located at 300 Pheasant Run which is protected by a security system including fire and burglar surveillance. Kimeragen's front door is protected with a magnetic lock requiring card access and at the end of the day a security barrier alarm system is powered up. Only authorized personnel will receive card access. Visitors and vendors must have the door opened to gain access.

Within the laboratory, radioisotope shall be kept in freezers which are lockable and which shall be marked with appropriate labels. The storage cabinet shall be locked at all times, except when materials are being added or disposed of. Only authorized users shall have access.

ITEM #7

Kimeragen, Inc. shall use a spreadsheet program to track material inventory. This program shall record the amount of isotope received, the amount used, and the amount placed in storage and/or disposed of by authorized users.

Authorized users must have the requisitions signed by the RSO who shall consult or have consulted the spreadsheet program to determine possession limits and the amount proposed for purchase.

ITEM #8

Kinderagen, Inc. shall use a survey meter (Ludlum model 3) with a thin sodium iodide crystal detector probe (Ludlum model 44-3) with which to detect iodine-125 contamination. The survey meter and probe shall be purchased from Ludlum Measurements, P.O. Box 810, 501 Oak Ave., Sweetwater, TX 79556 (License #LO-1963).

ITEM #9

Ludlum Measurements, P.O. Box 810, 501 Oak Ave., Sweetwater, TX 79556 holds License #LO-1963.

ITEM #10

Kimeragen, Inc. shall provide film badges for all laboratory personnel and shall provide in addition film rings for all users using ^{32}P and ^{33}P.

All dosimetry shall be provided by Landauer, Inc. of Glenwood, Il which is accredited by the National Voluntary Laboratory Accreditation Program. A copy of the certificate is attached hereto.

United States Department of Commerce
National Institute of Standards and Technology

NVLAP®

ISO/IEC GUIDE 25:1990
ISO 9002:1987

Certificate of Accreditation

LANDAUER, INC.
GLENWOOD, IL

is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:

IONIZING RADIATION DOSIMETRY

December 31, 1997
Effective through

For the National Institute of Standards and Technology
NVLAP Lab Code: 100518-0

NVLAP-01C (11-88)

Document #310

ITEM #11

RADIOACTIVE WASTE MANAGEMENT

Mixed Waste

Mixing of materials resulting in a mixture of radioactive and hazardous waste (e.g., heavy metals, organic solvents) is not sanctioned. Every effort must be taken to avoid creation of such mixed waste since proper disposal becomes extremely difficult.

Collection in the Lab

Radioactive waste is collected in the lab in labeled containers. Radioisotopes are segregated by radioisotope and whether liquid or solid. Solids are collected in metal or plastic containers lined with a plastic bag. Liquids are collected in plastic or other break proof containers.

Each container will have a tag and markings clearly indicating the radioisotope. After each addition to the container, enter the date and the millicurie quantity on the accompanying tag. When the container is full, it is transported to the waste area for either storage for decay or interim storage.

Liquids intended for interim storage must be solidified prior to their entering the storage area using approved methods such as Delaware Custom Media. Liquids for storage for decay may be stored as liquids.

Storage for Decay

Radioactive waste with half-lives less than 65 days are 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 waste storage area for decay. Following the prescribed decay period, the material will be surveyed with a survey meter for any detectable external beta or gamma activity. The waste will be disposed as non-radioactive waste only if the survey shows that the waste cannot be distinguished from the background.

During the final waste survey prior to disposal, record the following data:

- Radionuclide

- Date was out into storage for decay
- Date of final survey (must be at least 10 half-lives from initial date)
- Make, model and last calibration date of Geiger survey meter
- Background reading of Geiger survey meter reading
- Maximum Geiger survey meter reading
- Disposition of waste (e.g., trash, sewer, further decay, interim storage)
- Name of person doing the survey

Prior to disposal as non-radioactive waste, remove or obliterate all labels and references to radioactivity.

Waste with another hazard classification, such as medical waste or hazardous chemical waste, must be treated accordingly.

Transfer to Commercial Radioactive Waste Broker or Process

Radioactive waste with half-lives longer than 65 days may be packaged in 30 or 55 gallon drums for removal by a radioactive waste broker or processor licensed by the NRC or an Agreement State. Local brokers available for contract waste removal include Teledyne Brown Engineering Environmental Services, Westwood, NJ; and Radiac Research Corp., Brooklyn, NY. A log of cumulative activity of each isotope will be placed at each collection drum so that the total activities of each isotope can be determined. No liquids will be allowed in these drums. Liquid radioactive waste will be solidified in each laboratory using an approved solidification method such as cement or Delaware Custom Media.

Interim Storage

Radioactive waste with half lives longer than 65 days will be placed in interim storage if commercial disposal is unavailable. The volume of waste requiring interim storage is expected to be very small - approximately 1 55-gallon drum per year or less. Interim storage will be in a secure laboratory and designated as an interim radioactive storage area. Waste in interim storage will be stored in metal or plastic containers resistant to breakage, corrosion and leakage which meet DOT specification packaging. Metal drums will be lined with heavy duty plastic bags to avoid corrosion. Liquids will be solidified before placing into interim storage.

The storage area will be included in the same fire and security protection system that the rest of the building has.

Containers in interim storage will be surveyed at least every quarter for surface contamination, dose rate, physical leakage, package integrity (e.g., leaking, rusting, etc.) and inventory. The contamination survey will include, as a minimum, a swipe of every container and the floor both at the drums and at the door. Containers will be placed or moved so that all sides can be viewed during the routine inspection. A written record will be kept of these inspections.

Any container found or suspected to be leaking will be removed from its storage location and its contents transferred to a new container. Equipment for such a situation will be available, including spare drum(s), plastic bags, impervious gloves, disposable coveralls and shoe covers. After such a transfer, all equipment and affected areas will be radiologically surveyed according to normal survey procedures.

The Radiation Safety Officer will handle all transfers and surveys associated with the interim storage area. Any person who does all or part of these functions under the supervision of the Radiation Safety Officer will be trained in the following particulars: packaging, handling, placement, inspection, surveying and emergency response. Records of the training will be maintained.

The Emergency Notification Notice will be posted at the interim storage area as well as in the radiation work area(s).

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. Liquid waste disposal into the sewer drain is under the direct control of the Radiation Safety Officer who will pre-authorized each such disposal. The Radiation Safety Officer keeps records of all radioactive materials disposed into the sewer and calculates the average monthly concentrations and annual quantities for purposes of regulatory compliance.

The general procedure for disposal in the sewer is as follows.

- Sample the liquid from the container and assay for radioactive concentration.
- Calculate the quantity of each isotope in the container.
- Obtain the written authorization of the Radiation Safety Officer.
- Assure that only soluble radioactive material goes down the drain either by decanting it without mixing or by pumping it through a coarse filter.
- Return the container to the lab or storage area for re-use.

The sewer flow rate from the Kimeragen facility (not counting other occupants of the building) is estimated at 10,000 gallons per month based on actual water use by the previous occupants within the building. 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 and per year are calculated as follows:

Radionuclide	**Monthly Sewer Concentration Limit Table 3, (Appendix B, 20.1..1-2401), µCi/ml**	**Monthly Sewer Release Limit, based on 10,000 gal/mo., mCi**	**Annual Sewer Release Limit, mCi**
Hydrogen-3	0.01	378.8	5,000
Carbon-14	0.0003	11.4	1,000
Phosphorous-32	9E-05	3.4	1,000 combined.
Phosphorous-33	0.0008	30.3	
Sulfur-35	.0001	37.9	
Iodine-125	2E-05	0.8	

A sum of ratios method will be applied if more than one radionuclide is released. 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. Actual Concentrations will be calculated monthly when disposal occurs during that month.

Deregulated Radioactive Waste (liquid scintillation fluid and animal carcasses only)

The following waste may be disposed of as if it were not radioactive.

- 0.05 microcuries or less hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting.
- 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal.

Waste with another hazard classification, such as medical waste or hazardous chemical waste, must be treated accordingly. The Radiation Safety Office will keep records of all disposals made as deregulated waste.

ITEM #12

The Radiation Safety Officer's name, office phone and phone number to be used during off-hours will be specified on the Emergency Procedures form and in the lab as follows:

IN CASE OF EMERGENCY/SPILL CONTACT:

RAMESH KUMAR, PH.D. RADIATION SAFETY OFFICER

Office: 215-504-4444, extension 102

Home Phone number (which is located in the Radiation Safety Manual)

EMERGENCY PROCEDURES FOR SPILLS & PERSONAL CONTAMINATION

The Radiation Emergency Notification sheet in the front of this manual gives the phone numbers of local police, fire and medical emergency services, along with the night numbers of Kimeragen employees to be contacted in the event of an emergency in the laboratory.

All emergencies involving fire, explosion, flooding, etc. shall be brought under control promptly by trained personnel. **Fire fighting, first aid, and medical emergencies 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 spills and personal contamination will be handled according to the following emergency procedures.

Minor Spill of Radioactive Material

A Minor Spill is a spill of less than 1 mCi of p-32 or I-125, and less than 10 mCi of H-3, C-14, P-33 or S-35.

1. Notify all persons in the immediate vicinity of the spill, and tell them where the spill is and to keep away. If you must leave the area, post another person at the spill site or put a temporary sign at the spill.
2. First aid and other life saving actions take precedent over radiation contamination concerns.
3. Notify the Principal Radiation User, your supervisor or the Radiation Safety Officer.
4. Put on body badge dosimeter.
5. Put on impervious gloves and a lab coat.
6. Confine the spill with an absorbent material, being careful not to spread the material.
7. Use a radiation survey instrument to locate the extent of the spill.
8. If I-125 is spilled, keep liquid spill at a basic pH (above pH 8) or apply granular charcoal to absorb radioiodine vapors.
9. Decontaminate the area by cleaning with disposable absorbent towels.
10. Collect all contaminated materials in a plastic bag labeled with the standard radiation symbol and the words "Caution Radioactive Material." Dispose as radioactive waste.

11. Survey the area and all involved individuals with an appropriate radiation survey instrument. Continue cleaning until the meter shows no contamination above twice background.
12. Using filter paper swipes, survey the area for removable contamination. Continue cleaning until all areas are below 200 dpm per 100 square centimeters.

Major Spill of Radioactive Material

A Major Spill is a spill of more than 1 mCi of P-32 or I-125, or more than 10 mCi of H-3, C-14, P-33 or S-35.

1. Evacuate all persons in the immediate vicinity of the spill. If you must leave the area, post another person at the spill site or put a temporary warning sign at the door leading to the spill.
2. First aid and other life saving actions take precedent over radiation contamination concerns.
3. Notify the authorized user and the Radiation Safety Officer, one of whom will oversee the emergency actions.
4. Survey and decontaminate all persons who may have been contaminated. Remove contaminated clothing and wash any contaminated clothing and wash any contaminated skin with warm water and mild soap.
5. Put on body badge dosimeter and a ring dosimeter.
6. Put on impervious gloves and a lab coat. If necessary put on disposable shoe covers or rubbers.
7. Use a radiation survey instrument to locate the extent of the spill and to measure the dose rates.
8. Confine the spill with an absorbent material, being careful not to spread the material.
9. If I-125 is spilled, keep liquid spill at a basic pH (above pH 8) or apply granular charcoal to absorb radioiodine vapors.
10. Decontaminate the area by cleaning with disposable absorbent materials. Use remote tools such as long-handled mops to reduce personnel exposure.
11. Collect all contaminated materials in a plastic bag labeled with the standard radiation symbol and the words "Caution Radioactive Material." Dispose of as radioactive waste.
12. Survey the area and all involved individuals with an appropriate radiation survey instrument. Continue cleaning until the meter shows no contamination above twice background.
13. Using filter papers, survey the area for removable contamination. Continue cleaning until all areas are below 200 dpm per 100 square centimeters.

Personal Skin Contamination

Personal skin contamination is any amount of radioactive material on your hands, face or other skin areas, or contamination which may have soaked through your clothing to your skin.

1. Notify the your supervisor, the Principal Radiation User, and/or the Radiation Safety Officer, one of whom will oversee the decontamination process.

2. Use a radiation survey instrument (e.g., thin window Geiger ratemeter) to localize the areas of contamination.

3. If large areas of the body are contaminated, proceed to a water shower and begin decontamination immediately. .

4. Wash all areas of contamination beginning with mild warm soapy water and progressing to stronger soaps or hand cleaners. Do not abrade skin or crack skin with excessive cleaning.

5. Continue to survey the skin surface with the survey meter keeping records of the reading in cpm or dose rate.

6. Continue skin cleaning and surveying until no further progress is evident.

7. Keep a careful log of time, amounts of radioactivity, survey meter readings, etc.

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

ITEM #13

a. We have corrected the typographical error and our document now reflects 10 CFR 20.1906 (b),(c) and (d).

b. A Radioactive Waste Tag is attached hereto.

RADIOACTIVE WASTE TAG

Room: Principal Radiation User:

Please segregate all waste by radionuclide and type. Check only one box below:

	H-3	C-14	P-32	P-33	S-35	I-125
Dry Solid						
Aqueous Liquid						
Liquid Scintillation Solution - biodegradable						
Liquid Scintillation Solution - toluene/xylene						
Animal Carcasses						

Affix the form to every radioactive waste container. Record each deposit of radioactivity.

Activity mCi	Date	Generated by: (name)		Activity mCi	Date	Generated by: (name)

JAN 16 1997

Docket No. 030-34323
Control No. 124076

Jennifer Kmiec
Vice President, Administration
Kimeragen, Inc.
300 Pheasant Run
Newtown, PA 18940

Dear Ms. Kmiec:

This is in reference to your application dated January 3, 1997 requesting a Nuclear Regulatory Commission License. In order to continue our review, we need the following additional information:

1. Submit a description of the duties and responsibilities of your Radiation Safety Officer. The typical duties of a Radiation Safety Officer would be:

   a. To assess radiological hazards and prescribe, and ensure the implementation of, appropriate radiation safety precautions.

   b. To ensure that the use of licensed material is by or under the direct supervision of individuals specifically listed on your license.

   c. To ensure that all users (where appropriate) wear personnel monitoring equipment when using licensed materials.

   d. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

   e. To perform routine inspections of all laboratories using or storing licensed materials.

   f. To ensure that the terms and conditions of your license are met, and that all required records are maintained.

2. In your application, it appears that Patricia L. Avissar and Maryann C. Gruda, Ph.D., training and experience are not commensurate with your proposed use of iodine-125. If you wish to list them for the use of iodine-125, please describe their on-the-job or formal training, including the location and duration of the training. Training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring

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techniques and instruments (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of iodine-125 should include the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use.

3. Provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material.

4. 10 CFR 20.1101(c) requires that the licensee review the radiation protection program content and implementation at least annually. Submit a description of your program for performing the required annual review. It should include the following criteria:

   a. Senior management oversight of the radiation protection program. Specify the mechanisms that will be used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

   b. Review of the Radiation Safety Officer and staff performance. Specify the minimum qualifications for an individual who will perform this review, and confirm that the results will be reported to senior management.

   c. Audits by the Radiation Safety Officer and staff to determine user compliance with the requirements of the NRC license and your radiation protection program. Audits should include such topics as: reviews of users' inventory and survey records, evaluation of users' radiation safety procedures through observation and discussion, and performance of independent work area surveys.

5. Describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) to be made available at each location where licensed material will be used. Submit a description of the areas assigned for the receipt, storage, preparation, and measurement of licensed materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. For facilities where licensed materials may become airborne, include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Diagrams should be drawn to a specified scale, or dimensions should be indicated.

6. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application, you did not indicate how you will secure licensed material. Describe how you will preclude the unauthorized removal of licensed material from the place of storage and in unrestricted areas.

7. Describe your licensed material inventory, control and accountability program. Your inventory and control system should have the capability to assure that licensed material possession limits are not exceeded and that material is accountable throughout the institution at any given time.

8. Your equipment should include a survey instrument with a thin sodium iodide crystal detector probe to detect iodine-125 contamination. Please specify the instrument that will be used for this purpose.

9. Section 9 of the application list Ludlum Measurements, Inc., Sweetwater, TX as the firm to calibrate your survey instrument. Please specify the license number that authorizes the firm to perform calibration services.

10. Your application did not specify the type of personnel dosimetry you will provide (i.e. film or TLD). Please specify the type of personnel dosimetry you will provide and the frequency for changing the dosimeters.

11. Section 11 of the application describes an interim waste storage plan that is incomplete. Please submit a plan which contains all the information in the enclosed Information Notice 90-09. In particular, a description of the storage area and its fire and security protection systems.

12. Please submit a copy of the emergency procedures you will follow in case of spills or other types of accidents involving licensed materials. It is recommended that such procedures contain:

    a. instructions to be followed during minor spills,

    b. instructions to be followed during major spills, and

    c. confirm that your radiation protection officer's name, his office phone number, and a phone number to be used during off-duty hours will be specified on the procedures posted at your facility.

Appendix J of the enclosed regulatory guide may be helpful in preparing your response and provides procedures that are acceptable to the NRC.

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13. Some information in your application dated January 3, 1997 appears to be in error. Please provide correct information or provide additional information concerning the following:

    a. Section 10 of the application, you referenced 10 CFR 20.19069b,c,d as the requirement for surveying packages for external contamination within 3 hours of receipt. That is an incorrect listing of our regulation. The correct listing is 10 CFR 20.1906 (b), (c) and (d). Please make the necessary correction.

    b. Section 10 of the application, you stated that a form called Radioactive Waste Tag is included in this manual. The application does not have a form called Radioactive Waste Tag. Please submit the form for the application.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 124076. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5071.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By
Richard Gibson

Richard Gibson, Jr.
Division of Nuclear Materials Safety

Docket No. 030-34323
Control No. 124076

Enclosures:
1. 10 CFR Parts 19, 20, 21, 30, 71 and 171
2. Regulatory Guide(s) 10.7 and 10.8
3. Information Notice No. 90-09

DOCUMENT NAME: R.\WPS\DLTR\L3730363.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	RGibson/rxg							
DATE	01/16/97		01/ /97		01/ /97		01/ /97	

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KIMERAGEN, Inc.
Molecular Pharmaceuticals

January 3, 1997

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

LL 30367
030-34323
03620

RE: Kimeragen, Inc.
New Application for Materials

To Whom It May Concern:

Please find enclosed two copies of Kimeragen, Inc.'s Application for Material License and a check for $

Please process our application. If you have any questions, you may call Ramesh Kumar, Ph.D., RSO and VP at 215-504-4444, ext. 102.

If I can be of service, please call me at 215-504-4444, ext. 109.

Thank you.

Lisa Gail Malseed
Ass't to Vice President

124076

300 Pheasant Run Newtown, PA 18940 (215) 504-4444 Fax: (215) 504-4545

NRC FORM 313
(10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 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.

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 30363
030 - 34323
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)*

Kimeragen, Inc.
300 Pheasant Run
Newtown, PA 18940
Attn: Ramesh Kumar, Ph.D.

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

300 Pheasant Run
Newtown, PA 18940

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ramesh Kumar, Ph.D.

TELEPHONE NUMBER
215-504-4444 ext 102

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 WI[illegible]

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 $ 1500.00

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, 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
Jennifer Kmiec Vice President, Administration	Jennifer Kmiec	1/3/97

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (10-94)

PRINTED ON RECYCLED PAPER

OFFICIAL RECORD COPY ML 10 124076 JAN - 6 1997

SECTION 5

RADIONUCLIDE	CHEMICAL/PHYSICAL FORM	MAXIMUM AMOUNT POSSESSED AT ANY TIME, in millicuries
Hydrogen 3	Any	20
Carbon 14	Any	10
Phosphorous 32	Any	20
Phosphorous 33	Any	20
Sulfur 35	Any	20
Iodine 125	Iodinated compounds	10

SECTION 6

Authorized Uses of Radioactive Material

The radionuclides in the license will be used for the general purpose of laboratory research and development.

Iodine-125 will be obtained as pre-labeled "bound" compounds. There will be no radio-iodination conducted under this license.

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

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

SECTION 7

STATEMENT OF TRAINING FORM
(For Radiation Safety Officer)

Name: Ramesh Kumar, Ph.D. Title: Vice President

Formal Course on Radiation, if any:

Institution, City	Date and Duration	Name of course and short description
Paujob University, India	1975, one semester	Radiation Biophysics
Univ. of Illinois, Chicago	1982, 2 days	Radiation Training
National Cancer Inst. Fredrick, MD	1986, one day	Radiation Biology

Experience with Radiation
(Please list all types of work you have done with radioisotope or radiation)

Institution, City	Date and Duration	Radioisotope/Amount	Experiment/Use
Univ. of Illinois, Chicago	1981-85	p^{32},I^{125},H^3,Cr^{51},S^{35} (all about 5 mci)	Biology, Immun., Mol.Biol.
National Cancer Inst. Frederick, MD	1985-87	p^{32},I^{125},H^3,Cr^{51},S^{35} (all about 5 mci)	Biology, Immun., Mol.Biol.
Bristol Meyer Squibb Princeton, NJ	1988-91	p^{32}, I^{25},H^3,Cr^{51},S^{35} (all about 5 mci)	Biology, Immun., Mol.Biol.
DNX Princeton, NJ	1991-1994	p^{32}, H^3, S^{35} (all about 5 mci)	Biology, Immun., Mol.Biol.
Nextran Princeton, NJ	1994-1996	p^{32}, p^{33}, S^{35} (all about 5 mci)	Biology, Immun., Mol.Biol.

C.V. or resume attached.

CURRICULUM VITAE

Ramesh Kumar, Ph.D.
60 Yard Road
Pennington, NJ 08534

(609) 737-7319
Rameshkumar@msn.com

CAREER OBJECTIVE

Management of R&D focused on the discovery and development of therapeutic agents for genetic, metabolic and infectious diseases.

EXPERIENCE

15 years' experience in R&D; Molecular Biology, Transgenic animals, Gene-expression, Gene therapy.

ACHIEVEMENTS

Successfully supervised and coordinated goal-oriented research programs in pharmaceutical (Bristol-Myers Squibb) and biotechnology (DNX and Nextran) companies as well as at the National Cancer Institute. I have led scientific groups of 3-24 scientists and managed cross-functional collaborative projects. I have participated in an IPO and in identifying, evaluating and developing corporate partnerships with biotechnology and pharmaceutical companies

EMPLOYMENT

1996- Vice President, Technology & Product Development, Kimeragen Inc., Newtown, PA
Responsible for co-ordinating research, manufacturing, QC and other development activities aimed at commercializing a novel platform technology of gene based therapy.

1994-1996 Senior Director, Business Development, Nextran (an affiliate of Baxter International)
Responsibilities include strategic planning, technology assessment, in - and out-licensing, competitive intelligence and intellectual property management. Currently reporting to the CEO.

1993-94 Director, Xenotransplantation Program, DNX Biotherapeutics Inc.,

Princeton, NJ
R&D, corporate partnerships.

1991- 1993 Director, Blood Substitutes Research, DNX Corporation, Princeton, NJ
R&D, corporate partnerships.

1989-1991 Laboratory Head, Gene Expression Laboratory, Bristol-Myers Squibb Pharmaceutical Research Institute, Princeton, NJ
R&D in Cancer Therapeutics.

1989-1990 Research Staff, Department of Molecular Biology
Princeton University, Princeton, NJ

1986-1989 Postdoctoral Fellow, NCI-Frederick Cancer Research Facility
Basic Research Program, Frederick, MD

1986 Research Associate, Dept. of Microbiology & Immunology,
University of Illinois College of Medicine at Chicago, Chicago, IL

1981-1985 Teaching Assistant for Dental, Nursing, and Graduate Students,
University of Illinois Health Sciences Center, Chicago, IL

1985 Student Research Assistant, Bristol-Myers Project on Streptococcal Sore Throat

1978-1981 Lecturer in Microbiology, Panjab University, Chandigarh, India.

EDUCATION

1985	Ph.D. University of Illinois Health Sciences Center Chicago, IL	Microbiology & Immunology (Molecular Biology)
1979	Certificate Indian Council for Medical Research Bombay, India	Immunology

THESIS

Masters: Organ Specificity of Urinary Tract Pathogens: Nutritional and Immunological Studies, Panjab University, India.

Doctoral: Regulation of Gene Expression and Replication by Viral Enhancers, University of Illinois, Chicago

POST-DOCTORAL RESEARCH

1985-86	University of Illinois Dr. H. Reiter	Gene transfer in neuroblastoma cells
1986-88	National Cancer Inst. Dr. M. Barbacid	Oncogenes/Cancer
1988	National Cancer Inst. Dr. S. Hughes	Retroviruses

HONORS

1986	Phi Kappa Phi
1985, 1982	Graduate College Fellowship, University of Illinois
1976, 1978	University Medals for both Bachelors and Masters degrees
1976-1978	ICAR National Scholarship in Veterinary Microbiology
1973-1976	Alumni Association Scholarship for B.Sc.
1971	University Merit List for Pre-University Examination

AREAS OF INTEREST

Protein and peptide pharmaceuticals; Transgenic animals, Gene therapy; Anti-virals; Oncogenes; Cancer therapeutics; Molecular diagnostics, Regulatory aspects of drug development.

PROFESSIONAL MEMBERSHIPS

American Society for Microbiology
American Association for the Advancement of Science
American Association for Cancer Research

PEER-REVIEW

Reviewed papers for Cancer Research, Biotechniques, J. Virology, Oncogene, Technique, Oncogene Research, Biotechnology, Molecular and Cellular Biology, Gene, Molecular Carcinogenesis etc.

PUBLICATIONS

Over 40 papers and review articles in leading Molecular Biology and Oncology journals. Two manuals and one book published, and another book in preparation.

CITIZENSHIP: USA

STATEMENT OF TRAINING FORM
(For Principal Radiation User)

Name: Patricia L. Avissar Title: Associate Research Scientist

Formal Course on Radiation, if any:

Institution, City	Date and Duration	Name of course and short description
CSU, Fort Collins, CO	1987 One day class	General Radiation Safety
Bristol Meyers Squibb Princeton	1991 One day class	General Radiation Safety
Nextran, Princeton	1991-1996 1992-1996	Twice a year, training (1 hour) Radiation Safety Committee

Experience with Radiation
(Please list all types of work you have done with radioisotope or radiation)

Institution, City	Date and Duration	Radioisotope/Amount	Experiment/Use
CSU, Fort Collins, CO	1986-1989	S35, P32	Southern, Northern blots
Rutgers Univ.	1989-1991	S35, P32	Southern, Northern blots, sequencing
Bristol Meyers Squibb	1991	S35, P32	Southern, Northern blots,sequencing
DNX/Nextran Princeton	1991-1996	S35, P32	Southern, Northern blots, sequencing

C.V. or resume attached.

Patricia L. Avissar
32 Revock Road
East Brunswick, NJ 08816
Phone: (908) 613-9287 (H)
(609) 520-0300 (W)

EDUCATION: Hebrew University of Jerusalem, Israel
M.S. Genetics, *cum laude*, 1983
B.S. Biology, 1979

WORK HISTORY

- *RESEARCH*:

1991- present : **DNX Biotherapeutics/ Nextran, Princeton, New Jersey** - Research Associate
Cloning and expression of Human serum albumin in transgenic mice.
Detection of Human hemoglobin expression in transgenic animals.
Identification and characterization of peptide motifs responsible for hyperacute rejection.
Cloning and expression of Human thrombomodulin gene in transgenic animals.

1990 - 1991 : **Bristol- Myers Squibb, Dept. of Molecular Biology, Princeton, New Jersey** - Research Associate
Isolation and characterization of Drosophila Cytoplasmic Protein Tyrosine Phosphatase.

1988 - 1990 : **Rutgers University,**
Waksman Institute of Microbiology, Piscataway, New Jersey - Research Associate
Isolation and characterization of a cDNA clone of pathogenesis- related glucanase in tobacco.
Agrobacterium-mediated transformation of Arabidopsis.

1986 - 1988 : **Colorado State University, Dept. of Biology, Fort Collins, Colorado** - Research Associate
Determination of transcriptional and post-transcriptional regulation of phytochrome mRNA in oat seedlings.
Isolation of stress tolerance genes from cultures of *Distichlis spicata*.
Transformation of barley by direct injection of DNA into plant tillers.

1984 - 1988 : **Agricultural Research Organization, Dept. of Plant Genetics and Breeding, Bet-Dagan, Israel**
Research Associate
Protoplast fusion. Isolation of methotrexate-resistant lines of petunia and tobacco.

1983 - 1984 : **Hebrew University of Jerusalem, Faculty of Agriculture, Rehovot, Israel** - Research Associate
Determination of the physiological response of plant stomata to environmental conditions.

1979 - 1983 : **Hebrew University of Jerusalem, Dept. of Genetics, Faculty of Agriculture, Rehovot, Israel**
M.S. Thesis: " The genetic consequences of inter-karyotypic hybridization in the *Vicia sativa* complex".

- *MANAGEMENT*

7/95 - 1/96 : **Nextran, Princeton , New Jersey**
Organization of the GLP laboratory, preparation and implementation of Standart Operating Procedures.

1994- present: **Nextran, Princeton , New Jersey**
Member of the Radiation Safety Committee, assisting Radiation Safety Officer in preparation, review and implementation of radiation safety-related regulations.

1988 - 1990 : **Rutgers University. Waksman Institute of Microbiology, Piscataway, New Jersey**
Lab management (purchasing of supplies, daily organization and maintenance of the lab facilities).

- *TEACHING*

1980 - 1983 : Hebrew University of Jerusalem, Dept. of Genetics, Faculty of Agriculture, Rehovot, Israel
Teaching Assistant: Introduction to Genetics; Applied Genetics
Introduction to Cytogenetics; Advanced Cytogenetics
Statistical Principles in Experimental Design

SKILLS

Molecular Biology:
Gene cloning and manipulation, Restriction analysis
DNA and RNA isolation and purification, Southern and Northern hybridization
Library screening
PCR technology for detection and generation of DNA fragments, PCR cloning
RT-PCR, RFLP-RT-PCR, Site-directed mutagenesis
Sequencing and computer analysis (MacVector; GCG)
Pulse Field Gel Electrophoresis
Protein gels (PAGE), IEF gels, Western blotting, In vitro translation, Immunoprecipitation
Screening of epitope library, ELISAs, Complement Mediated Lysis

Computer Skills:
Macintosh: Word, Canvas, Excel, MacVector
IBM: Microsoft Windows, Word, Excel

Tissue Culture: (Plants) :
Development and maintenance of plant cell lines

PUBLICATIONS:

- Kooyman, D.L, McClellan, S.B, Parker, W., Avissar, P.L., Velardo, M.L., Platt, J.L. and Logan, J.S., 1996. Identification and Characterization of a Galactosyl Peptide Mimetic. Transplantation. Rapid Communication. Vol. 61, 851-855, No. 6.
- Avissar, P.L. and Kumar, R., 1993. Expression of the Human Serum Albumin Locus in Transgenic Mice carrying > 100Kb recombinant P1 Phage DNA. Poster presented at SAB meeting, Princeton.
- Avissar, P.L., Okabe, J., Sharma, A. and Kumar, R., 1992. PCR Detection and Quantitation of of Human Hemoglobin Expression in Transgenic Mice and Pigs. Poster presented at the " Eight Conference on Hemoglobin Switching", Seattle.
- Colbert, J.T., Costigan, S.A., Avissar, P.L., and Zhao, Z., 1991. Regulation of Phytochrome Gene Expression. Jour. Iowa Acad. Sci. 98 (2): 63-67.
- Colbert, J.T., Costigan, S.A., Avissar, P.L., Christensen, A.H., Peters, N.K. and Quail, P.H., 1987. Transcriptional and Post-transcriptional Regulation of Phytochromr mRNA Abundance in Oats Seedlings. Jour. of Cellular Biochemistry, sup11B, p.51.
- Avissar, R., Avissar, P.L., Mahrer, Y. and Bravdo, B.A., 1985. A Model to Simulate Response of Plant Stomata to Environmental Conditions. Agric. For. Meteorol. 34: 21-29.

REFERENCES:

Upon request

STATEMENT OF TRAINING FORM
(For Principal Radiation User)

Name: Maryann C. Gruda, Ph.D. Title: Research Scientist

Formal Course on Radiation, if any:

Institution, City	Date and Duration		Name of course and short description
Bristol-Meyers Squibb	11/92	One day	Radiation Safety Training-indiv.
	10/93	½ day	Annual Review Radiation Safety
	10/94	½ day	Annual Review Radiation Safety

Experience with Radiation
(Please list all types of work you have done with radioisotope or radiation)

Institution, City	Date and Duration	Radioisotope/Amount	Experiment/Use
University of Pitts	9/86 - 9/87	C^{14}/.5 mCi	Enzymatic Assay
University of PA	9/87 - 8/92	C^{14}, S^{35}, P^{32}	DNA/RNA label, Enzymatic Assay
Bristol Myers Squibb	11/92 - 1/96	C^{14}, S^{35}, P^{32}	DNA/RNA label, Enzymatic Assay

C.V. or resume attached.

Maryann C. Gruda

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Yardley, PA 19067

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EDUCATION

Ph.D., Molecular Biology, 1992, UNIVERSITY OF PENNSYLVANIA

Dissertation: "Identification of Cellular Transcription Factors Involved in Simian Virus 40 (SV40) T-antigen Transcriptional Activation of the SV40 Late Promoter."

B. S., Microbiology, 1987, UNIVERSITY OF PITTSBURGH, *magna cum laude*

RESEARCH EXPERIENCE

Postdoctoral Research:

Advisor: Dr. Rodrigo Bravo
Bristol-Myers Squibb Pharmaceutical Research Institute,
Department of Oncology, 1992-1996

Study: Expression patterns of Fos proteins during development. Analysis of FosB knockout and cFos/FosB double knockout mice. Gene expression in knockout cells. Regulation of phosphorylation during the cell cycle. Microinjection of purified antibodies.

Graduate Research:

Thesis Advisor: Dr. James C. Alwine
University of Pennsylvania Graduate Group of Molecular Biology, School of Medicine, 1988 -1992.

Study: Transcriptional regulation of gene expression by T-antigen. Identified regulatory promoter elements. Expressed cloned cellular transcription factors *in vivo*. Purified bacterially-expressed proteins to study protein-protein and protein-DNA interactions.

Graduate Rotations:

Advisor: Dr. Barbara Hoffman-Lieberman
Department of Biochemistry, School of Medicine, Spring 1988
Study: Expression vector cloning to study promoter activity.

Advisor: Dr. William C. Lawrence
School of Veterinary Medicine, Fall 1987
Study: Marker Rescue of mutants in Bovine Herpes Virus-1 Thymidine Kinase gene.

Undergraduate Research:

Advisor: Dr. Iain M. Campbell
University of Pittsburgh, Department of Biology, Sept 1985 - Aug 1987
Study: Purification and study of enzyme kinetics of Phenylalanine Ammonia Lyase in Penicillium brevicompactum. Prepared polyclonal antibodies.

Honors: Merck Fellowship (1990 -1992)
NIH Training Grant in Virology (1988 - 1990)

Expertise: Regulation of gene expression, transfections, quantitative RT-PCR, RNAse protection, immuno-histochemistry & flourescence, protein expression and purification, cloning, antibody purification, Western blots, immunoprecipitation, microinjection, DNA binding assays, kinase assays, mutagenesis.

PUBLICATIONS AND ARTICLES

Alwine, J.C., M.C. **Gruda**, G.J. Gallo, G. Gilinger J. Manupello and J. Picardi. 1989. Simian Virus 40 Large T-Antigen affects the DNA-binding characteristics of Simian transcription factors: Mechanisms for T-Antigen-mediated transcriptional activation, in "Common Mechanisms of Transformation by Small DNA Viruses: (L.P. Villareal, Ed.) pp185-194.

Gallo, G.J., M.C. **Gruda**, J.R. Manuppello, and J.C. Alwine. 1990. Activity of Simian DNA-binding factors is altered in the presence of Simian Virus 40 (SV40) early proteins: Characterization of factors binding to elements involved in activation of the SV40 Late Promoter. *J. Virology* 64:173-184.

Gruda, M.C., and J.C. Alwine. 1991.Simian Virus 40 (SV40) T-Antigen transcriptional activation mediated through the Oct/SPH region of the SV40 Late Promoter. *J. Virology* 65:3553-3558.

Gruda, M.C., J.M. Zabolotny, J.H. Xiao, I. Davidson, and J.C. Alwine. 1993. Transcriptional activation by Simian Virus 40 Large T-Antigen: Interactions with multiple components of the transcription complex. *Mol. Cell Biol.* 13: 961-969.

Gruda, M.C., K. Kovary, R. Metz and R. Bravo. 1994. "Regulation of Fra-1 and Fra-2 phosphorylation differs during the cell cycle of fibroblasts and phosphorylation in vitro by MAP kinase affects DNA binding activity." *Oncogene* 9:2537-2547.

Estus, S., W.J. Zaks, R.S. Freeman, M.C. **Gruda**, R. Bravo, and E.M. Johnson, Jr. 1994. Altered gene expression in neurons during programmed cell death: Identification of c-*jun* as necessary for Neuronal apoptosis. *J. Cell Biology* 127: 1717-1727.

Gruda, M.C., J. van Amsterdam, C.A. Rizzo, S.K. Durham, S. Lira, and R. Bravo. 1996. Expression of FosB during development: normal development of FosB knockout mice. *Oncogene* 12, 2177-2185.

Dorfman, K., D. Carrasco, M.C. **Gruda**, C. Ryan, S. Lira, and R. Bravo. 1996. Disruption of the erp/mkp-1 gene does not affect mouse development: normal map kinase activity in ERP/MKP-1 deficient fibroblasts. *Oncogene,* 13, 925-931.

Gruda, M.C., A. Lewin, J.K. Loy, B. Speigelman and R. Bravo. Increased susceptibilities to gastric epithelial hyperplasia and epilepsy in FosB and cFos knockout mice. *In preparation.*

SECTION 8

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 will keep records of all radiation safety training.

The basic Radiation Safety training session will consist of a 2 to 4 hour didactic presentation covering the following topics:

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

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. Kimeragen will give 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 a Radiation Safety Officer and will consist of about 15-30 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.

SECTION 9

RADIATION DETECTION INSTRUMENT

The facility will obtain a liquid scintillation counter. Current plans call for the purchase of a Wallac, Inc. Model 1409-012 Research Counting System which is a modern advanced liquid scintillation analyzer with automatic external standard calibration using ACSS+ and digital spectral analysis. This or an equivalent liquid scintillation will be used to count samples for various beta and electron capture radionuclides including carbon-14, hydrogen-3, phosphorus-32, phosphorus-33, sulfur-35 and iodine-125.

The licensee will purchase one (1) radiation survey instrument consisting of a Ludlum Measurements, Inc. hand-held battery-operated Model 3 ratemeter with a Model 44-9 end-window pancake-style Geiger detector probe. This Geiger probe has a window thickness of 1.7 mg/cm^2 of mica, with an active open area of 11.5 cm^2. It has a background of about 40 cpm and a sensitivity range of 100 to 500,000 cpm. This, or an essentially equivalent 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. The detection efficiencies for selected radionuclides are listed below:

Radionuclide	**Survey Instrument**	**Appropriate Detection Efficiency**
tritium	Ludlum ratemeter with	zero
carbon-14	Model 44-9 end-window	5%
phosphorous-32	pancake-style Geiger	35%
phosphorous-33	detector probe	15% (estimate)
sulfur-35		5%
iodine-125		1% (estimate)

RADIATION INSTRUMENTATION CALIBRATION

The liquid scintillation analyzer will be used for research as well as for radiation protection purposes. The liquid scintillation analyzer contains a built-in calibration method called ACSS+ as well as digital spectral analysis and a spectral library including spectra for carbon-14, hydrogen-3, phosphorous-32, sulfur-35, and iodine-125. The instrument is auto-calibrating and normalizing.

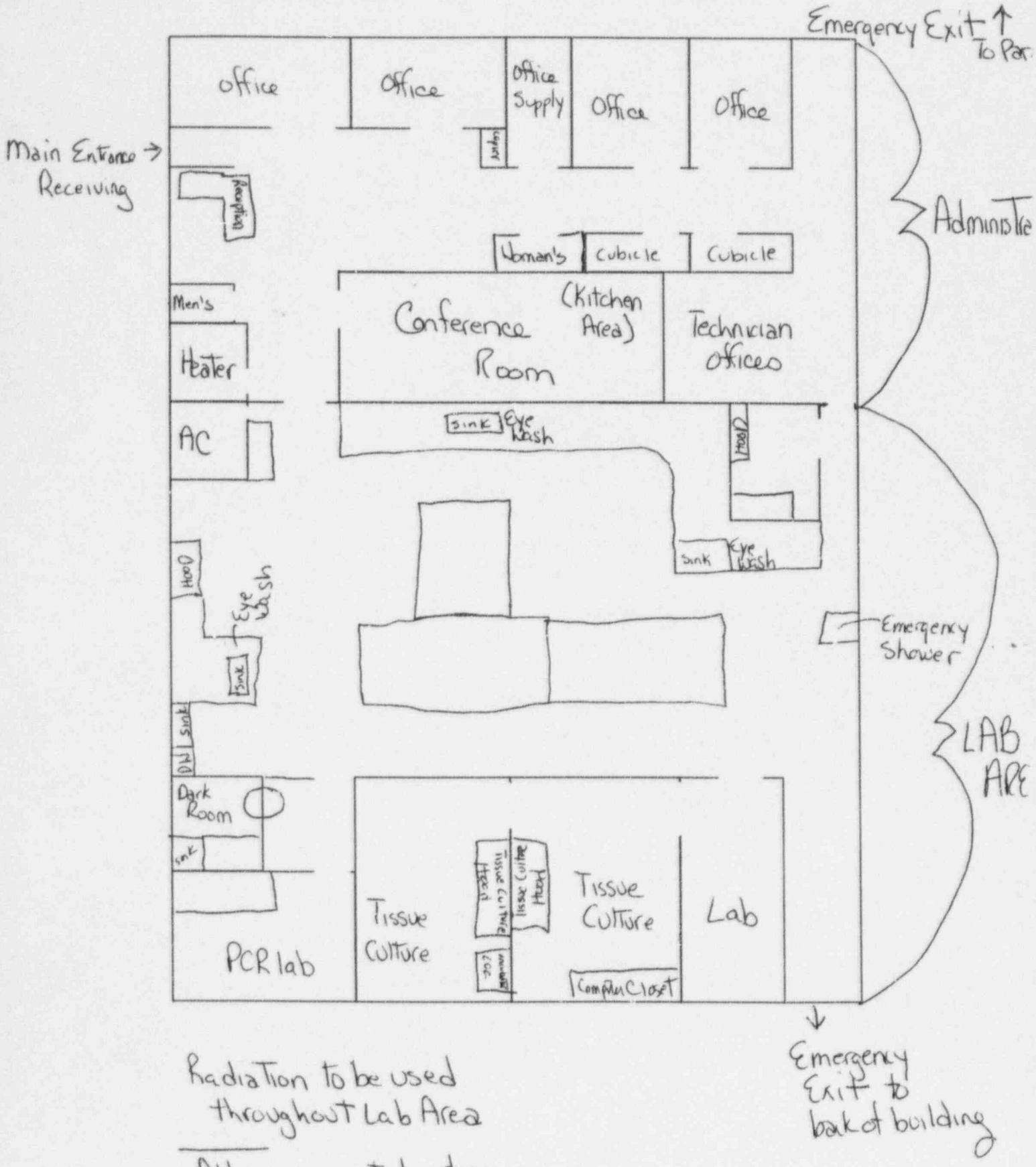
The Geiger radiation survey meter will be calibrated annually and after any repairs. The calibration shall be done by the manufacturer or by a reputable commercial calibration lab. The calibration lab, which must be licensed, is currently Ludlum Measurements, Inc., Sweetwater, TX.

PERSONNEL MONITORING

Whole body dosimeter badges and ring dosimeters will be obtained from Landauer, Inc., Glenwood, Ill or another commercial dosimetry vendor. The vendor must 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 on a quarterly basis, or more frequently as determined by the Radiation Safely Officer.

All persons working in the laboratory areas of the facility are required whole body radiation dosimeters. Persons who use millicurie quantities high energy beta emitters such as phosphorous-32 are required to wear a ring dosimeter when working with this material.

Note on Bioassay: Persons will not use more than 1 mCi of I-125 at a time on an open bench or more than 10 mCi in a hood at any one time. Since this is less than 10% of the Table 1 values given in NRC regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131" no thyroid bioassays are necessary.


Emergency Exit ↑ to Par
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Janitor
Administrative
Women's
Cubicle
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Men's
(Kitchen Area)
Conference Room
Technician offices
Heater
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Eye wash
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Sink
Emergency Shower
LAB ARE
Dark Room
sink
Tissue Culture Hood
Tissue Culture
Lab
Tissue Culture
PCR lab
Computer
Comput Closet
Emergency Exit to back of building
Radiation to be used throughout Lab Area
All receiving to be done at front door

SECTION 10

KIMERAGEN'S RADIATION SAFETY PROGRAM

PERSONNEL MONITORING

Whole body dosimeter badges and ring dosimeters will be obtained from Landauer, Inc., Glenwood, Ill or another commercial dosimetry vendor. The vendor must 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 on a quarterly basis, or more frequently as determined by the Radiation Safely Officer.

All persons working in the laboratory areas of the facility are required whole body radiation dosimeters. Persons who use millicurie quantities high energy beta emitters such as phosphorous-32 are required to wear a ring dosimeter when working with this material.

Note on Bioassay: Persons will not use more than 1 mCi of I-125 at a time on an open bench or more than 10 mCi in a hood at any one time. Since this is less than 10% of the Table 1 values given in NRC regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131" no thyroid bioassays are necessary.

PREGNANT RADIATION USER

Women who are or become pregnant may, if they wish, declare themselves to be pregnant by submitting in writing to the Radiation Safety Officer a statement that she is pregnant and the estimated date of conception. Making such a declaration of pregnancy is voluntary on the part of the woman.

For a declared pregnant woman, Kimeragen will ensure that the dose to the embryo/fetus during the entire pregnancy, due to occupational exposure, does not exceed 0.5 rem. This includes both internal and external dose and is about 10% of the dose allowed to occupationally exposed adults. Further information on dose to the embryo/fetus is found in the Nuclear Regulatory Commission regulation 10 CFR 20.1208.

Upon receiving a written declaration from a declared pregnant woman, the Radiation Safety Officer will review her potential for radiation exposure in the workplace and take steps to keep her exposure as low as reasonably achievable (ALARA).

GENERAL INSTRUCTION TO ALL RADIATION USERS

All persons who work with radioactive materials must follow the following general instructions.

1. Lab coats are available and must be worn when using radioactive materials. Other devices such as gloves, remote grippers, benchtop shields, plastic shields, remote pipettors, absorbent paper, and similar equipment are available and shall be used whenever appropriate.

2. Open vials or containers of more than 1 mCi of iodine-125 shall be handled in a chemical fume hood.

3. Phosphorous-32 in quantities greater than 1 mCi shall be handled utilizing plastic, glass or other shielding whenever possible. P-32 in quantities greater than 1 mCi shall be handled using impervious gloves and eye protection such as safety glasses or goggles. Persons handling such beta emitters in quantities greater than 1 mCi shall wear a ring dosimeter under a glove in addition to the required body badge dosimeter. When using phosphorous-32 in quantities greater than 1 mCi, a "dry run" before the performance of unfamiliar procedures shall be done to preclude unexpected complications. The Radiation Safety Officer will be present during the initial run of new procedures.

4. Contamination surveys must be performed at least monthly in all radioisotope areas. Additionally, each user shall use a radiation survey meter to check for contamination and relative radiation levels during each experiment. Principles of radiation protection (e.g., time, distance, and shielding) shall then be applied to keep radiation exposures as low as reasonably achievable.

5. Iodine-125 may be not be moved from room to room unless it is in a closed container or protected against vaporization into the air.

6. 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.

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

8. All persons working with radioactive materials will wear whole body radiation dosimeters ("film badges") clipped to the shirt pocket or collar. Persons who use millicurie quantities of phosphorous-32 will be issued and shall wear a ring dosimeter when working with this material. Dosimeters will be collected by the Radiation Safety Officer or his/her designate and exchanged for new dosimeters. All persons issued radiation dosimeters are responsible for their proper wearing and routine exchange.

9. Radioactive waste will be collected in the laboratory. Different isotopes shall not be mixed in the same waste collection container. Radioisotopes with half lives less than 65 days will be held in the laboratory or in the waste storage room for decay for at least 10 half lives. Only the Radiation Safety Officer or his/her specific designate may authorize the disposal of decayed waste. All waste containers will be labeled with the standard "Caution Radioactive Materials" label and with 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. Liquid waste not held for decay (e.g., tritium and carbon-14) will be solidified using an approved solidification methods prior to transferring to the waste storage room. Radioactive waste may be disposed into the sewer only if it is soluble material or readily dispersible biological material, and only with the authorization of the Radiation Safety Officer.

10. 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/her 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.

LABORATORY RADIATION SAFETY RULES

The following radiation safety rules will be observed by all radiation users when licensed radioactive materials.

1. Wear a lab coat whenever pipetting or otherwise dispensing radioactive solutions.

2. Always wear disposable gloves while handling licensed materials when the reasonable possibility of contamination exists.

3. Never pipette radioactive solutions by mouth.

4. Absolutely no eating, drinking or smoking where licensed material stored or used.

5. Do not store food, drink or personnel effects in areas where licensed materials is stored or used.

6. Never store food or beverages in refrigerators or freezers which also contain radioactive materials.

7. Use disposable plastic-backed absorbent sheets or impervious cleanable surfaces (e.g., plastic trays or Teflon coatings) to contain radioactive solutions if spilled.

8. Use a hand-held radiation survey meter during and after all radionuclide operations to follow to progress of the radioactive species during the experiment and to identify contamination. (Tritium cannot be monitored this way.)

9. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using a portable survey meter. (Tritium cannot be monitored this way.)

10. For tritium, conduct an "operational" swipe survey by wiping with a filter paper or cotton swab selected surfaces such as bench tops, floor, radiation user's hands and fingers, etc. Swipes shall be counted by liquid scintillation analysis and results reviewed as soon as possible, but in any event by the next business day. The survey shall be required at the end of every major radionuclide experiment if more than 1 mCi was used, and daily if more than 10 mCi was used. Removable contamination more than 1000 dpm per 100 cm^2 shall be promptly decontaminated. Removable contamination levels more than 5000 dpm per 100 cm^2 will be reported promptly to the Radiation Safety Officer and decontaminated. Record your survey data.

11. When required, always wear your body badge and/or ring dosimeter while in areas where licensed materials are used or stored.

12. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.

13. Never put radioactive waste in the ordinary garbage receptacle.

14. Secure all licensed material when not under the constant surveillance and immediate control of the user.

15. Notify your supervisor or the Radiation Safety Officer of any spills except those of a very minor nature.

16. Radionuclide work shall be done in a chemical fume hood whenever the possibility exists if airborne contamination because of rapid evaporation, flaking, dusting or aerosolization of the radioactivity.

17. 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.

18. Glassware, and similar re-usable equipment, shall be thoroughly rinsed twice into the liquid radioactive waste collection container before placing into the normal lab cleaning process.

PURCHASE OF RADIOACTIVE MATERIALS

The Radiation Safety Officer shall authorize each purchase of radioactive materials. The Radiation Safety Officer shall assure that for each purchase:

- The facility license limit for the radionuclide will not be exceeded.
- The PRU is authorized to use that radionuclide.
- If the package will require a DOT shipping label (i.e., White I, Yellow II, or Yellow III), arrangements are made for the incoming package contamination survey to be done within 3 hours.

RECEIPT & OPENING OF PACKAGES

Package Receiving Procedures

Incoming packages of radioactive materials will be logged into the appropriate "Radioactive Package Log" immediately upon receipt in the laboratory. The log entry will indicate the isotope, the amount in mCi or μCi, the vendor or sender, the name of the person who will use it, the date, and the initials of the person entering the information. Read the packing list and the package labeling and compare the isotope and quantity with the ordering information to verify that the material ordered is the material received.

Packages of radioactive material will be received at the main entrance door and moved as soon as possible to the laboratory.

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 according to the requirements of 10 CFR 20.19069b,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 Kimeragen's building. (If received during non-business, 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 filter paper, swipe all sides of the outer package, covering about 300 square centimeters.
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. Divide the dpm by the area swiped in square centimeters (e.g., 300 cm^2) to calculate dpm per square centimeter.
7. If the net radioactivity on the outside of the package is greater than 22 dpm per square centimeter, immediately take the following action:

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

Phone: 601-337-5000
Fax: 601-337-5393/5368/5234/5269

8. If the net radioactivity on the outside of the package is greater than 2.2 dpm per square centimeter, 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 contamination 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.

Note: Incoming packages will not be monitored for radiation levels as part of the receiving procedure because possession limits for all radionuclides are below the Type A quantities as defined in 10 CFR 71.4. Thus, all incoming packages will be below Type A quantities and do not require radiation level monitoring as per 10 CFR 1906(b)(2).

Package Opening Procedures

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

1. Keep the package on a disposable absorbent pad, impervious plastic sheet, or non-porous cleanable surface in the laboratory.

2. Wearing gloves and a lab coat, open the package, monitoring contamination levels on packaging materials and container surfaces with a suitable radiation survey meter.
3. Dispose of any contaminated packaging material as radioactive waste.
4. 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.
5. 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.

POSTING, LABELING AND TAGGING

General Facility Posting

The following documents must be posted at locations where they can be observed by persons engaged in licensed activities. These are permanent postings and must be replaced if missing or defaced. A suitable location might be at the entrance to the main lab or in the common employee break/lunch room.

- NRC Form 3, "Notice to Employees"
- Notice of availability of Nuclear Regulatory Commission regulations, license, license conditions and operating procedures.
- Any notice of violation , civil penalty or order from the Nuclear Regulatory Commission, and the company's response. (These must be posted within 2 days of receipt and remain posted for 5 working days or until all violations are corrected.)

Radiation Use and Storage Areas

Labs, rooms, areas and storage locations (cabinets, drawers, refrigerators, etc.) where radioactive materials are stored or used shall be posted with a sign containing the standard radiation symbol and the words, "Caution, Radioactive Materials."

Radiation Areas

Radiation Areas are any location where an individual could receive a dose in excess of 5 mrem in any 1 hour at 30 centimeters from the source of radiation. Radiation Areas shall be posted with a sign containing the standard radiation symbol and the words, "Caution, Radiation Areas."

Containers

Every container of radioactive material shall bear a label with the standard radiation symbol and the words, "Caution, Radiation Materials." The label must also indicate the radionuclide, an estimate of the quantity, and the date of the estimate of the quantity.

Empty containers with no radioactive contamination shall have any radiation warning label removed or defaced.

Radioactive Waste Containers

Containers used to accumulate radioactive waste shall have a tag or sheet attached on which person. will record the radionuclide, the quantity, the person's name and the date. A form called Radioactive Waste Tag is included in this manual.

TRANSPORT AND SHIPMENT OF RADIOACTIVE MATERIALS

If radioactive materials are transported or shipped off site, the process must adhere to the US Department of Transportation (DOT) regulations for shipping hazardous materials, and Kimeragen must verify in writing that the recipient is properly and currently licensed to receive the material.

DOT Hazardous Materials Shipping Regulations

The DOT regulations for shipping radioactive materials are found in regulation 49 CFR 173.401-478 (Subpart I). Most shipments will fall within the "limited quantity" exception which is covered by regulation 49 CFR 173.421. Limited quantities are defined in the table below:

Radionuclide	**A_2 Quantity millicurie**	**Maximum per Package for "Limited Quantity" Exception, millicurie**	
		Liquid	Solid
H-3	20,000	2	20
C-14	60,000	6	60
P-32	30,000	3	30
P-33	unlisted	unlisted	unlisted
S-35	60,000	6	60
I-125	70,000	7	70

Packages containing less than the above Limited Quantity amount are exempted from the requirements for specification packaging, shipping papers and certification, marking and labeling. However the following conditions must be adhered to:

- The material must be packaged in strong, tight packages that will not leak any of the radioactive materials during conditions normally incident to transportation.
- The radiation level at any given point on the external surface of the package does not exceed 0.5 millirem per hour.

- The removable radioactive surface contamination on the external surface of the package does not exceed 6600 dpm per 300 cm^2 area.

- The outside of the inner packaging bears the label "Radioactive".

- The following certification notice must be included in or on the package, with the packing list forwarded with the package.

> From Kimeragen, Inc. "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package - limited quantity of material, UN2910."

License Verification of Transfer of Radioactive Material

Kimeragen must positively verify that the recipient is properly and currently licensed to receive the material in accordance with Nuclear Regulatory Commission regulation 10 CFR 30.41. While various types of recipient and forms of verification are acceptable, the following basic procedure should handle most shipments of radioactive material:

- Obtain and read a copy of the recipient's radioactive material license. It can be issued by the Nuclear Regulatory Commission or an Agreement State.

- Verify that it allows the type, form and quantity of radioactive material to be transferred.

Maintain a copy of the recipient's license for future reference.

SECTION 11

RADIOACTIVE WASTE MANAGEMENT

Mixed Waste

Mixing of materials resulting in a mixture of radioactive and hazardous waste (e.g., heavy metals, organic solvents) is not sanctioned. Every effort must be taken to avoid creation of such mixed waste since proper disposal becomes extremely difficult.

Collection in the Lab

Radioactive waste is collected in the lab in labeled containers. Radioisotopes are segregated by radioisotope and whether liquid or solid. Solids are collected in metal or plastic containers lined with a plastic bag. Liquids are collected in plastic or other break proof containers.

Each container will have a tag and markings clearly indicating the radioisotope. After each addition to the container, enter the date and the millicurie quantity on the accompanying tag. When the container is full, it is transported to the waste area for either storage for decay or interim storage.

Liquids intended for interim storage must be solidified prior to their entering the storage area using approved methods such as Delaware Custom Media. Liquids for storage for decay may be stored as liquids.

Storage for Decay

Radioactive waste with half-lives less than 65 days are 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 waste storage area for decay. Following the prescribed decay period, the material will be surveyed with a survey meter for any detectable external beta or gamma activity. The waste will be disposed as non-radioactive waste only if the survey shows that the waste cannot be distinguished from the background.

During the final waste survey prior to disposal, record the following data:

- Radionuclide

- Date was out into storage for decay
- Date of final survey (must be at least 10 half-lives from initial date)
- Make, model and last calibration date of Geiger survey meter
- Background reading of Geiger survey meter reading
- Maximum Geiger survey meter reading
- Disposition of waste (e.g., trash, sewer, further decay, interim storage)
- Name of person doing the survey

Prior to disposal as non-radioactive waste, remove or obliterate all labels and references to radioactivity.

Waste with another hazard classification, such as medical waste or hazardous chemical waste, must be treated accordingly.

Transfer to Commercial Radioactive Waste Broker or Process

Radioactive waste with half-lives longer than 65 days may be packaged in 30 or 55 gallon drums for removal by a radioactive waste broker or processor licensed by the NRC or an Agreement State. Local brokers available for contract waste removal include Teledyne Brown Engineering Environmental Services, Westwood, NJ; and Radiac Research Corp., Brooklyn, NY. A log of cumulative activity of each isotope will be placed at each collection drum so that the total activities of each isotope can be determined. No liquids will be allowed in these drums. Liquid radioactive waste will be solidified in each laboratory using an approved solidification method such as cement or Delaware Custom Media.

Interim Storage

Radioactive waste with half lives longer than 65 days will be placed in interim storage if commercial disposal is unavailable. The volume of waste requiring interim storage is expected to be very small - approximately 1 55-gallon drum per year or less. Interim storage will be in a secure laboratory and designated as an interim radioactive storage area. Waste in interim storage will be stored in metal or plastic containers resistant to breakage, corrosion and leakage which meet DOT specification packaging. Metal drums will be lined with heavy duty plastic bags to avoid corrosion. Liquids will be solidified before placing into interim storage.

The storage area will be included in the same fire and security protection system that the rest of the building has.

Containers in interim storage will be surveyed at least every quarter for surface contamination, dose rate, physical leakage, package integrity (e.g., leaking, rusting, etc.) and inventory. The contamination survey will include, as a minimum, a swipe of every container and the floor both at the drums and at the door. Containers will be placed or moved so that all sides can be viewed during the routine inspection. A written record will be kept of these inspections.

Any container found or suspected to be leaking will be removed from its storage location and its contents transferred to a new container. Equipment for such a situation will be available, including spare drum(s), plastic bags, impervious gloves, disposable coveralls and shoe covers. After such a transfer, all equipment and affected areas will be radiologically surveyed according to normal survey procedures.

The Radiation Safety Officer will handle all transfers and surveys associated with the interim storage area. Any person who does all or part of these functions under the supervision of the Radiation Safety Officer will be trained in the following particulars: packaging, handling, placement, inspection, surveying and emergency response. Records of the training will be maintained.

The Emergency Notification Notice will be posted at the interim storage area as well as in the radiation work area(s).

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. Liquid waste disposal into the sewer drain is under the direct control of the Radiation Safety Officer who will pre-authorized each such disposal. The Radiation Safety Officer keeps records of all radioactive materials disposed into the sewer and calculates the average monthly concentrations and annual quantities for purposes of regulatory compliance.

The general procedure for disposal in the sewer is as follows.

- Sample the liquid from the container and assay for radioactive concentration.
- Calculate the quantity of each isotope in the container.
- Obtain the written authorization of the Radiation Safety Officer.
- Assure that only soluble radioactive material goes down the drain either by decanting it without mixing or by pumping it through a coarse filter.
- Return the container to the lab or storage area for re-use.

The sewer flow rate from the Kimeragen facility (not counting other occupants of the building) is estimated at 10,000 gallons per month based on actual water use by the previous occupants within the building. 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 and per year are calculated as follows:

Radionuclide	**Monthly Sewer Concentration Limit Table 3, (Appendix B, 20.1..1-2401), µCi/ml**	**Monthly Sewer Release Limit, based on 10,000 gal/mo., mCi**	**Annual Sewer Release Limit, mCi**
Hydrogen-3	0.01	378.8	5,000
Carbon-14	0.0003	11.4	1,000
Phosphorous-32	9E-05	3.4	1,000 combined.
Phosphorous-33	0.0008	30.3	
Sulfur-35	.0001	37.9	
Iodine-125	2E-05	0.8	

A sum of ratios method will be applied if more than one radionuclide is released. 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. Actual Concentrations will be calculated monthly when disposal occurs during that month.

Deregulated Radioactive Waste (liquid scintillation fluid and animal carcasses only)

The following waste may be disposed of as if it were not radioactive.

- 0.05 microcuries or less hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting.
- 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal.

Waste with another hazard classification, such as medical waste or hazardous chemical waste, must be treated accordingly. The Radiation Safety Office will keep records of all disposals made as deregulated waste.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 3
FEE CATEGORY: ---
EXP. DATE: 0
FEE COMMENTS: ---
DECOM FIN ASSUR REQD: -

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: KIMERAGEN, INC.
RECEIVED DATE: 970106
DOCKET NO: 3034323
CONTROL NO.: 124076
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $1500.00
CHECK NO.: 1855

3. COMMENTS

SIGNED M. A. Perkins
DATE 1/6/97

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

1. FEE CATEGORY AND AMOUNT: 3M $1,500

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

3. OTHER ---

SIGNED ---
DATE ---

I (97)
Log Box 2
Reminder
Check No. 1855
Amount $1,500
Fee Category 3M
Type of Fee APP
Date Check Rec'd 1/10/97
Date Completed
By: BB