MATERIALS LICENSE

Amendment No. 05

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

301258

Licensee	
1. Gelman Sciences	In accordance with application dated April 4, 1996 3. License Number 21-26088-01 is renewed in its entirety to read as follows:
2. 600 South Wagner Road Ann Arbor, MI 48103-9019	4. Expiration Date October 31, 2001
	5. Docket or Reference No. 030-31413

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. 60 millicuries
B. Phosphorus-32	B. Any	B. 60 millicuries
C. Sulfur-35	C. Any	C. 30 millicuries
D. Iodine-125	D. Any	D. 120 millicuries
E. Phosphorus-33	E. Any	E. 90 millicuries

9. Authorized Use:

A. through E. For in-vitro laboratory research and development as defined by 10 CFR 30.4.

CONDITIONS

10. Licensed material shall be stored only at the licensee's facilities located at 600 South Wagner Road, Ann Arbor, Michigan.

11. The Radiation Safety Officer for this license is Linda S. Belkowski, Ph.D.

12. Licensed material shall be used by, or under the supervision of, Linda S. Belkowski, Ph.D. or Kevin Seely.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-26088-01
Docket or Reference Number: 030-31413
Amendment No. 05

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

14. Licensed material shall not be used in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

15. This license does not authorize commercial distribution of licensed material.

16. 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 April 4, 1996 attached to letter dated October 3, 1996; and

B. Letter dated October 3, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 23 1996

By Carlton R Mathis
Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 2
FEE CATEGORY: 3P
EXP. DATE: 19961130
FEE COMMENTS: STORAGE/10/11/95/1YR
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GELMAN SCIENCES
RECEIVED DATE: 960418
DOCKET NO: 3031413
CONTROL NO.: 301258
LICENSE NO.: 21-26088-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: ~~X~~ 1700 * ADDL INFO
CHECK NO.: ~~X~~ 221283 397976-R9

3. COMMENTS

SIGNED D. Hersey
DATE ~~4-29-96~~

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 05 IS ENTERED (✓))

1. FEE CATEGORY AND AMOUNT: 3P FEE NOT REQUIRED

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

3. OTHER

SIGNED JC
DATE 5/6/96

RECEIVED
MAY 13 1996
REGION III

1996 MAY -9 PM 4:44

Log May 4 M
Remitter
Check No. 221283
Amount $1700 Returned ck. ADD'L info.
Fee Category 3P
Type of Fee Ren
Date Check Rec'd 5/6/96
Date Completed 5/6/96
By: JC

NRC FORM 313 (10-8, 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

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)*
   - [ ] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [X] C. RENEWAL OF LICENSE NUMBER 21-26088-01

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

Gelman Sciences Inc.
600 S. Wagner Road
Ann Arbor, MI 48103-9019

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

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
Robert Blackburn

TELEPHONE NUMBER
313-936-1582

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

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY
AMOUNT ENCLOSED $ 1700

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
Gary Yezbick, Vice President, Human Resources	Gary Yezbick	4/4/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
	ADD'L 6.6	2D	$397.96		FEE NOT REQUIRED
APPROVED BY				DATE	RECEIVED APR 18 1996
				31258	

NRC FORM 313 (10-94)

PRINTED ON RECYCLED PAPER

REGION III

600 South Wagner Road
Ann Arbor, MI 48103-9019 USA
FAX (313) 913-6114
(313) 665-0651

GelmanSciences

April 3, 1996

Attn: Ms. Evelyn R. Matson
NRC
Nuclear Materials Licensing Branch
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Evelyn:

Enclosed is our application for material license as requested in your letters dated November 22, 1995, and August 1, 1995.

We have submitted the application as a renewal of license number 21-26088-01. You requested that we state that we are providing the additional information to Control Number 399364. Please inform me as to whether this was necessary since we submitted a renewal.

Sincerely,

Robert Blackburn
Gelman Sciences Inc. Consulting RSO

Enclosure: Application for Material License

NRC APPLICATION

TABLE OF CONTENTS

ITEM 5

RADIOACTIVE MATERIAL

RADIONUCLIDE	CHEMICAL/PHYSICAL FORM	POSSESSION LIMIT
H-3	Amino Acids/Liquid	20 mCi
P-32	Nucleotides/Liquid	20 mCi
P-33	Nucleotides/Liquid	30 mCi
S-35	Nucleotides/Liquid	10 mCi
I-125	NaI/Liquid or Protein/Liquid	40 mCi
H-3	Solid and/or Liquid Waste	40 mCi
P-32	Solid and/or Liquid Waste	40 mCi
P-33	Solid and/or Liquid Waste	60 mCi
S-35	Solid and/or Liquid Waste	20 mCi
I-125	Solid and/or Liquid Waste	80 mCi

ITEM 6

PURPOSE(S) FOR WHICH

LICENSED MATERIAL WILL BE USED

a. See the following "Radioisotope Applications at Gelman Sciences Inc."

b. For each radionuclide listed in ITEM 5, typical experiments will involve 1 mCi or less of activity. I-125 iodinations will be performed in the fume hood.

c. Licensed material will be used in the MAIN LABORATORY (Figure 1).

ITEM 6 (Continued)

RADIOISOTOPE APPLICATIONS AT

GELMAN SCIENCES INC.

Gelman Sciences Inc. (GSI) is a manufacturer of microporous membranes for industrial and laboratory use. Depending upon the nature of the application, GSI is able to provide microporous membranes which have either a low or high affinity for biomolecules (protein, drugs, nucleic acids). Hence, in addition to characterizing a membrane based on physical properties, our quality control operation also characterizes membranes based on binding capacity. GSI currently uses a dye binding test to evaluate binding capacity. Briefly, anionic and cationic dyes are passed through membranes and the resultant color is used as an indicator of the membrane's binding (charge) capacity. Unfortunately, dye-binding capacity does not always correlate with biomolecule-binding capacity.

Isotopes at GSI will be used as part of our quality control program to determine the binding capacity of microporous membranes. Isotopes will be used to "tag" proteins and nucleic acids. In one assay, radioactive biomolecules will be passed through membrane disks, washed and counted in a beta or gamma counter. The concentration of biomolecules bound to the membrane can be determined by knowledge of the specific activity of the preparation. In another assay, various radiolabeled molecules will be dotted onto membranes via a dot blot apparatus. The membranes will be washed and exposed to x-ray film to obtain a hard copy of radioactive spots. This assay will provide us with additional information on binding capacity but also provide information on the membrane's affinity and sensitivity.

Isotopes will also be used by GSI in application-oriented testing. Membranes designed for molecular biological research will be evaluated by most of the current techniques. These include Southern blots, Northern blots, plaque lifts and colony lifts. Hybridization with radiolabeled DNA probes will be performed to provide us with information on how a given lot of membrane can be expected to perform at the user level.

Lastly, isotopes will be used in experiments which GSI is requested to perform by customers. Occasions arise when customers desire the binding characteristics of a particular membrane for a given substance (drugs, growth factors). In such cases, radiolabeled substances will be purchased from authorized manufacturers and used in assays similar to those for binding capacity determinations. Briefly, the radiolabeled substance will be passed through membrane disks, washed and counted.

ITEM 7

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

Robert Blackburn will function as consultant RSO. Mr. Blackburn has extensive experience (Curriculum Vitae and Statement of Training and Experience attached) using radionuclides and activities for the requested uses.

Authorized users will be designated by the RSO.

ROBERT B. BLACKBURN

11758 Louis Lane
Whitmore Lake, MI 48189
313 426-7724

EDUCATION

Bachelor of Science in Biology, December, 1984.
The University of Michigan, Ann Arbor

TECHNICAL PAPERS

"The Growth of Micro-Fungi After Cobalt 60 Radiation" in Ukraine Botany Journal, 1994, Vol. 51, #6. P.A. Volz, D.J. Najarian, R.B. Blackburn, S.P. Wasser.

"Development of Radiation-Hard Scintillators"
F. Markley, D. Woods, A. Pla-Dalmau, G. Foster, R. Blackburn

PROFESSIONAL MEMBERSHIP

American Association of Tissue Banks

CONFERENCES /COURSES

12TH Annual American Association of Tissue Banks Mtg., ASTM International Workshop On Dosimetry For Radiation Processing, Analtech's Step by Step Thin Layer Chromatography, & 19TH Annual American Association of Tissue Banks Mtg.

EMPLOYMENT EXPERIENCE

08/87-Present

Research Assistant I & II, Research Associate I & II
The University of Michigan-Phoenix Memorial Lab(PML), Ann Arbor, MI

- Supervise, coordinate, and perform all aspects of radiopharmaceutical production at PML for the department of Nuclear Medicine. Includes ordering, receiving, using, waste disposal & storage, and inventory of radioisotopes up to 1 Curie according to NRC license regulations, radiochemical synthesis, quality control, quality assurance, process validation, customer relations, radiation safety, and domestic and international authorized shipper of radioactive materials.
- Evaluate and implement laboratory radiation safety practices.
- Knowledgeable in detecting removable and non-removable surface contamination.
- Versed in radioactive and other Hazardous Goods Transportation regulations including the testing and approval of shipping containers.
- Manage, coordinate, operate, supervise, and train qualified personnel to operate the Cobalt 60 irradiation facility which is licensed for 25k curies.
- Write and organize the extensive Cobalt 60 radioactive material license.
- Develop, assist, and collaborate in research and experimental programs as a specialist or technical expert.
- Develop training programs for staff in use and operation of Cobalt 60 irradiator and radiopharmaceutical production.

EMPLOYMENT EXPERIENCE (Continued)

- Interpret and assure compliance with FDA, NRC, & DOT regulations including direct handling of federal inspections.
- Design, evaluate, and implement equipment & supplies to modify or improve the Cobalt 60 irradiator and radiopharmaceutical production.
- Maintain instrument validation and calibration records.
- Supervise and perform the maintenance of laboratories, equipment, and Cobalt 60 irradiator.
- Write and revise procedures.
- Prepare/compile monthly and annual reports related to current programs and costs.

05/82-08/87 Research Assistant Ann Arbor Nuclear, Incorporated, Ann Arbor, MI

- Prepared, irradiated, and analyzed chemical samples that could serve as a source of energy for production of synthetic fuel with possible space applications.
- Developed and implemented improved experimental techniques and apparatus.
- Gained skills in the use of chemical vacuum-lines, radioactivity and neutron activation analysis counting equipment.
- Gained skills in sterile and culture techniques, electrophoresis slab gel preparation and techniques, thermoluminescense dosimetry, correct care and handling of lab animals, and methods of injecting, dissecting, and perfusing lab animals.
- Knowledgeable in the use of Mettler and micro balances, ultracentrifuges, CO_2 incubator, ultraviolet, polarizing, and dissecting microscopes, lypholizer, and cell harvester for use in determining viability of cell lines.

09/80-05/82 Research Assistant The University of Michigan, Chemistry Department, Ann Arbor, MI

- Neutron activation analysis of ancient/medieval coins and Uranium/Thorium impurity levels in computer chip support materials.

RSS-101A
7/91

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Blackburn, (LAST) Robert (FIRST) Bradley (MIDDLE) Soc. Sec. #: 367-86-1720 Sex: M

Job Title: Research Associate II Birthdate: 06/12/62 Work Phone: 6-1582

Department: PML/Nuclear Medicine Authorized User: Reed R. Burn/Donald Wieland, PhD

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

(X) ( ) Attended the University of Michigan - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: 04/82, 09/84, and 09/87

(X) ( ) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) • Principles/Practices of Radiation Protection: Reactor Operator Training, Ford Nuclear Reactor, Aug 88 - Feb 91; Reactor Operator March 91

(X) ( ) • Biological Effects of Radiation: Incorporated within BS degree in biology. Reactor Operator Training(FNR) Aug 88 - Feb 91; Reactor Operator March 91

(X) ( ) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: Same as above

(X) ( ) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: Same as above

(X) ( ) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: Atomic/Nuclear structure, radiochemistry, and nuclear physics incorporated within BS degree.

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: International workshop on dosimetry for radiation processing, 09/89. Training sessions given by Health Physicist at Phoenix Memorial Laboratory.

(X) ( ) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: May 87-Present I-131, I-125 in amounts up to 1 Ci, I-123 up to 150 mCi, Dy-165 up to 10 mCi and Br-82 for research development and manufacture of radiopharmaceuticals. Cs-137(5 mCi), Ra-226 (1 mCi), Ba-133(10 mCi), Tc-99M(1 Ci), and Tc-99(10 mCi) used for calibrating instruments. April 82-Present Co-60(25,000 Ci) used for gamma irradiations. Short lived isotopes of Ti,Cl, U, Th, K, Na, Ag, Au, in activation analysis.

Robert Blackburn — Signature

JAN 23 '95 — Date

Please return to: Radiation Safety Service
1101 North University Building (1057)
FAX NUMBER: 763-1185

ITEM 8

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

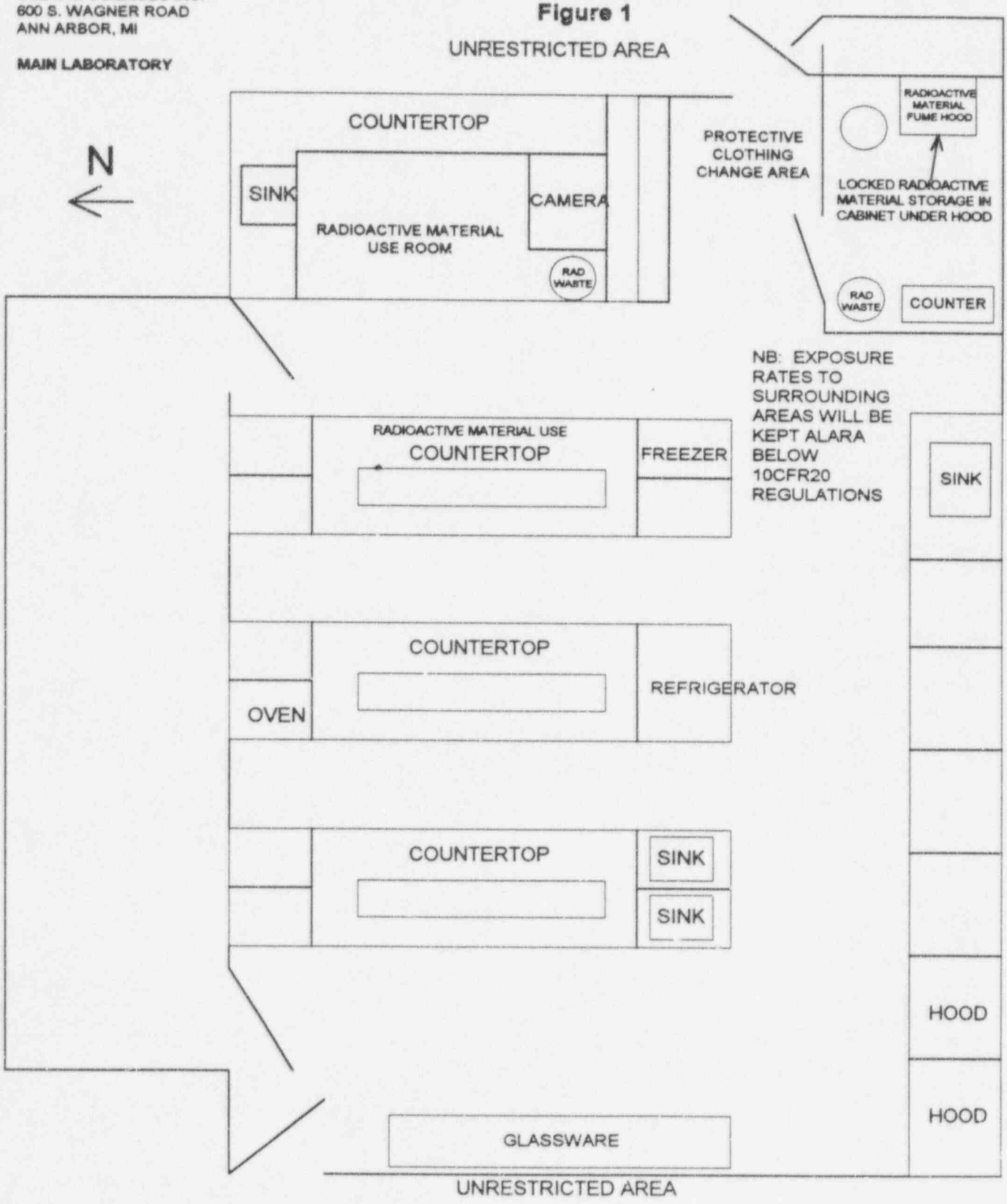
See 3.1 of attached Gelman Sciences document number MP-05350-3.

GELMAN SCIENCES INC.
600 S. WAGNER ROAD
ANN ARBOR, MI

MAIN LABORATORY

ITEM 9 FACILITIES AND EQUIPMENT

Figure 1



ITEM 9 (CONTINUED)

FACILITIES AND EQUIPMENT

a. Survey Equipment

Eberline E-120 with HP-260 thin window "Pancake" G.M. probe and attached lamp mantle check source.

b. Counting Equipment

Pharmacia Model 1209 Liquid Scintillation Counter.

c. Contamination Control

Absorbent paper or pads
Disposable Gloves
Fume Hood (for I-125 use)
Laboratory Coats
Shoe/Foot Covers
Shaving Cream or equivalent radiation decontamination foam
Radiation Decontamination Liquid
Soft Finger Scrub Brush

d. Remote Handling

Remote Pipettes
Remote Handling Tongs
Syringes

e. Shielding

Lead
Lead "pigs"
Lucite face-shield (for P-32 use)

ITEM 10

RADIATION SAFETY PROGRAM

See attached Gelman Sciences Inc. document number MP-05350-3.

ITEM 11

WASTE MANAGEMENT

See 3.13 of attached Gelman Sciences Inc. document number MP-05350-3.

1.0 PURPOSE:

To provide for the purchase, receipt, storage, safe use, and disposal of radioactive material.

2.0 SCOPE:

All radionuclides used in applications in the main laboratory at Gelman Sciences, Ann Arbor office.

3.0 PROCEDURE:

3.1 Personnel Training Program

3.1.1 All "occupationally exposed" individuals will be instructed:

3.1.1.1 During initial orientation before assuming duties with, or in the vicinity of, radioactive materials.

3.1.1.2 During annual refresher training.

3.1.1.3 Whenever there is a significant change in duties, regulations, or in the terms of the license.

3.1.2 Instructions will be in verbal and written form and will include the following subjects:

3.1.2.1 Applicable regulations and license conditions.

3.1.2.2 Areas where radioactive material is used or stored.

3.1.2.3 Potential hazards associated with radioactive material in each area where the employees will work.

3.1.2.4 Appropriate radiation safety procedures.

3.1.2.5 The licensee's in-house work rules.

3.1.2.6 Each individual's obligation to report unsafe conditions to the Radiation Safety Officer (RSO).

3.1.2.7 Appropriate response to emergencies or unsafe conditions.

3.1.2.8 The worker's right to be informed of occupational radiation exposure and bioassay results.

3.1.2.9 Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

3.1.3 Successful completion of the training program will be based on: (1) the opinio[illegible]ie RSO that the trainee is qualified to use radioactive materials and (2) a score of 80% o[illegible]ore on a written examination which will be sent to the department director for retention (Ref. QSR-02240-5 and DF-05350-1).A copy shall also be forwarded to Human Resources for retention in the employee's personnel file.

3.1.4 The RSO will schedule briefings and educational sessions to inform workers of As Low As is Reasonably Achievable (ALARA) program efforts.

Approvals:

Applications Development Date

Effective: APR 3 [illegible]

FOR INFORMATION ONLY
NOT VALID FOR
PRODUCTION OR PROCESS

3.1.5 The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

3.2 Radiation Safety Officer

3.2.1 Review of Proposed Users and Uses

3.2.1.1 The RSO will thoroughly review the qualifications of each proposed user with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

3.2.1.2 When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposures ALARA.

3.2.1.3 The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigation levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigation levels are exceeded.

Table I: Investigation Levels

	Body Part Exposed	Level I (mrems per calendar quarter)	Level II (mrems per calendar quarter)
1.	Whole body; head and trunk; active blood forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body	750	2250

3.2.2 Annual and Quarterly Review

3.2.2.1 Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis.

3.2.2.2 Quarterly review of occupational exposures The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 3.5 of this program and will prepare a summary report for management.

3.2.2.3 Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for management.

3.2.3 Reviewing Instances of deviation from Good ALARA Practices

3.2.3.1 The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will attempt to determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3.3 Authorized Users

3.3.1 New Methods of Use Involving Potential Radiation Doses

3.3.1.1 The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.

3.3.1.2 The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

3.3.2 Authorized User's responsibility to Supervised Individuals

3.3.2.1 The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

3.3.2.2 The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

3.4 Individuals Who Receive Occupational Radiation Doses

3.4.1 Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

3.4.2 Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

3.5 Establishment of Investigation Levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigation levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigation levels that we have adopted are listed in Table I. These levels apply to the exposure of individual workers.

The RSO will review and record on form NRC-5, "Current Occupational External radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 20.401 of 10 CFR Part 20. The following actions will be taken at the investigation levels as stated in Table I:

3.5.1 Personnel dose less than Investigation Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table I values for the Investigation Level I.

3.5.2 Personnel dose equal to or greater than Investigation Level I but less than Investigation Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigation Level I and will report the results of the reviews to the individual and to management following the quarter when the dose was recorded. If the dose does not equal or exceed Investigation Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

3.5.3 Personnel dose equal to or greater than Investigation Level II

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigation Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's form NRC -5 or its equivalent will be presented to the management upon completion of the investigation.

3.5.4 Reestablishment of Investigation Levels to Levels Above Those Listed in Table I

In cases where a worker or group of workers' doses need to exceed an investigation level, a new, higher investigation level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented. The RSO will review the justification for and must approve or disapprove all revisions of investigation levels.

3.6 Personnel Monitoring Program

3.6.1 All individuals who are occupationally exposed to radiation and may receive greater than one-tenth the quarterly permissible whole-body limits will be issued a film or TLD whole body monitor.

3.6.2 All individuals who handle radioactive material on a regular basis and may receive greater than one-tenth of the quarterly permissible extremity limit will be issued a film or TLD finger monitor.

3.6.3 Other individuals who are exposed to radiation on an occasional basis such as loading dock, housekeeping, and security personnel, will not normally be issued exposure monitors.

3.6.4 External thyroid bioassays will be performed in accordance with *Regulatory Guide 8.20 "Application of Bioassay for I-125 and I-131."* Processes involving I-125 will be performed within a fume hood.

3.6.5 Whole-body film badges and TLD finger rings will be purchased from Landauer or some other vendor accredited by the National Institute of Standards and Technology. The badges will be changed out on a monthly basis by the individual user, the RSO, or his designate, and the reports supplied filed by the RSO. A photocopy of the most current report (minus personal information) will be posted in the laboratory and the original will be filed in the Radiation Safety Officer's files.

3.7 Survey Meter Calibration and Check

3.7.1 All survey instruments will be calibrated every six months and checked using a check source before each use. Survey instruments will be calibrated in accordance with Reg. Guide 10.8, Appendix B by:

3.7.1.1 The manufacturer.

3.7.1.2 GTS Instrument Services (NRC License No. 37-28097-01, Exp. 11/30/98)

3.7.1.3 Medical Physics Consultants (NRC License No. 21-2015301).

3.7.1.4 Any licensee authorized to perform survey meter calibrations as a service.

3.8 Rules for the Safe Use of Radioactive Materials

3.8.1 The RSO will ensure that authorized users, workers and ancillary personnel will:

3.8.1.1 Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

3.8.1.2 Wear disposable gloves at all times while handling radioactive materials.

3.8.1.3 Either after each procedure or before leaving the area, monitor hands and clothing for contamination in a low background area with GM. survey meter.

3.8.1.4 Not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.

3.9.1.14 Cleanup: Use disposable gloves and remote handling tools when possible.

3.9.1.15 Survey: Survey the area with a low-range GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

3.10 Package Order and Receipt Procedures

3.10.1 The RSO or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

3.10.2 The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

3.10.2.1 Written records will be made that identify the date received, authorized user, isotope, chemical form, activity, and supplier.

3.10.2.2 The above records will be checked to confirm that material received was ordered through proper channels.

3.10.3 All deliveries will be made during normal working hours. Radioactive packages will be delivered to the approved user or designee at the approved laboratory of use.

3.11 Procedure for Opening Packages Containing Radioactive Material

3.11.1 The RSO or designee will ensure that personnel open packages containing radioactive material as follows:

3.11.1.1 Put on gloves to prevent hand contamination.

3.11.1.2 Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3.11.1.3 Measure the exposure rate from the package at 1 meter (Transport Index, T.I.) and at the package surface. If the rate is significantly higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour (mrem/hr). Packages with the "White I" labels should be ≤0.5 mrem/hr at the package surface. Packages with the "Yellow II" labels should be ≤ 50 mrem/hr at the package surface.

3.11.1.4 Wipe the external package and remove the wipe sample to a low-background area. Assay the wipe with the thin-end window GM meter (liquid scintillation counter for H-3) to determine if there is any removable activity. If there is any contamination, notify the RSO.

3.11.1.5 Follow the steps listed below when opening the package:

- Remove the packing slip.
- Open the outer package following the supplier's instructions, if available.
- Open the inner package and verify that the contents agree with the packing slip.
- Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
- If anything unusual is noticed, stop and notify the RSO.

3.11.1.6 Verify that the material received is the material ordered.

3.11.1.7 Monitor the packaging material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding or recycling.

3.11.1.8 Record the receipt and all readings taken.

3.12 Area Survey Procedures

3.12.1 Surveys for contamination and ambient exposure rates will be performed as follows:

3.12.1.1 All areas where radioactive materials are used will be surveyed for ambient radiation exposure rates on each day of use and swipe tested for contamination each week of use. Area surveys will be performed with the GM survey meter and swipes counted on the liquid scintillation counter calibrated to read in dpm.

3.12.1.2 All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

3.12.1.3 Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h.

3.12.1.4 Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 200 dpm.

3.12.1.5 The trigger level for exposure rate surveys will be rates above the normal background reading for that area.

3.12.1.6 The trigger level for removable contamination surveys will be the detection of values greater than three standard deviations above normal background on repeat surveys.

3.12.1.7 Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

3.12.1.8 A record shall be kept of all survey results on Swipes Test Record, DF-05350-4. The record will include:

- Location, date and type of equipment used.
- Initials of the person conducting the survey.
- Drawing of the area surveyed.
- Trigger levels keyed to the location on the drawing.
- Results keyed to the location on the drawing.
- Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

3.12.1.9 The RSO or designee will review the survey results on a quarterly basis for conformance to certain action levels.

3.13 Waste Disposal

3.13.1 Radioactive materials, in the form of liquids, solids and vials, will be disposed of into clearly marked drums in the biotechnology laboratory.

3.13.1.1 Liquid radioactive waste may be disposed of into the sanitary sewer system at a rate not to exceed 1/10 of the limits of Table II of Appendix B of 10 CFR 20. Records will be kept of the date, radionuclide, estimated activity released, estimated concentration, and site of release. This mode of disposal will be in addition to those stated in 3.13.1.

3.13.1.2 Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20.303.

3.13.1.3 As necessary, the material shall be transferred to a sealed 55 gallon drum, sealed by designated personnel, and taken to the Radioactive Waste Storage Area. The material will be held there until the required holding period has elapsed.

3.13.2 Radioactive material with a half life less than 90 days will be decayed for 10 half-lives in approved containers. The current storage sites for containers are the biotechnology laboratory and the chemical storage building. Full waste containers may be removed to the chemical storage facility for decay. These containers will be clearly labeled as to radionuclide, date of last addition, and date when the material may be checked for disposal as non-radioactive waste.

3.13.3 Prior to disposal, each container will be monitored as follows:

3.13.3.1 Low-range GM survey meter will be checked for proper operation.

3.13.3.2 Waste will be monitored in a low-level area.

3.13.3.3 Any shielding around the container will be removed.

3.13.3.4 All surfaces of each individual container will be monitored.

3.13.3.5 Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.

NOTE: Waste Management Inc. doesn't require defacing labels of waste to be incinerated.

3.13.4 Radioactive waste with a half-life greater than 90 days will be disposed of by transfer to an authorized recipient.

4.0 REFERENCE DOCUMENTATION:

4.1 QSR-02240-5, Training

4.2 DF-05350-1, Training Record

4.3 DF-05350-4, Swipes Test Record

4.4 U.S. N.R.C. Regulatory Guide 10.7

5.0 REVISION HISTORY:

Section(s) Changed	Changed By
3.2.3.1, 3.5.2, 3.5.3, 3.6.4, 3.6.5, 3.8.1.7, 3.8.1.8 3.9.1, 3.10.2.1, 3.10.3, 3.11.1.3, 3.11.1.4, 3.11.1.5, 3.11.1.7, 3.11.1.8, 3.13.1.3, 3.13.2, 3.13.3.5; 3.2..3 deleted; 3.13.4 added	L. Scheer

DATE: 4-22-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: ~~John Madera~~ Dixie

LICENSEE: GELMAN

LICENSE NUMBER: _____

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

397976 RENEWAL ?

[X] Additional Information to Control No. ~~397964~~ _____.
Process in as a new action, additional information, and no fee required.

[ ] Process as new licensing action. Review has already been started on Control No._____ and this information cannot be combined with current in-house action.

[ ] Can be combined with Control No. _____. Review has not been started.

[ ] Appears to be a(n)_____.

[ ] Appears to be information for the license file - file it.

[ ] Licensee is adding Nuclear Pharmacists.
Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

[ ] Licensee is adding authorized users.
A check is included _____. No check is included _____.
Amendment is necessary _____. Amendment is not necessary _____.
(Information for the license file)

[ ] Other:_____

Thank You For Your Help!!! 02/02/95

NRC FORM 677 (10-94)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

COPY

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

Gelman Sciences, Inc.
ATTN: Mr. Gary Yezbick
600 S. Wagner Road
Ann Arbor, Michigan 48103-9019

TYPE OF ACTION

- [ ] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [x] AMENDMENT TO LICENSE

REQUESTED DATE: April 4, 1996

LICENSE NUMBER: 21-26088-01

CONTROL NUMBER: 301258

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE $

PAYMENT RECEIVED $

AMOUNT DUE $

- [ ] Your request was received without the prescribed application fee.
- [ ] We received your Check No. _____ in the amount of $_____. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your licensed program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [x] Enclosed is Check No. 221283 which accompanied your request. The fee is not required because:
- [ ] We received your Check No. _____ in payment of the fee.
- [x] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated 12/22/94, Control No. 397976.
- [ ] Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [ ] License No. _____, Amendment No. ____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the licensee was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield	5/9/96	/ /

DISTRIBUTION
OC/DAF/RF
LFDCB R/F (2)
Pending Fee File
Region 3

DATE: May 9, 1996

NRC FORM 677 (10-94)

OCT 24 1996

Gary Yezbick
Gelman Sciences
600 South Wagner Road
Ann Arbor, MI 48103-9019

Dear Mr. Yezbick:

Enclosed is Amendment No. 05 renewing your NRC Material License No. 21-26088-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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

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

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

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

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

301258

c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

d. Change ownership of your organization.

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

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

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

Sincerely,

Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 21-26088-01
Docket No.: 030-31413

Enclosure: Amendment No. 05

DOCUMENT NAME: M:\03031413.CL6

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

OFFICE	DNMS/RIII	N							
NAME	EMATSON:jaw								
DATE	10/3/96								

OFFICIAL RECORD COPY

600 South Wagner Road
Ann Arbor, MI 48103-9019 USA
Fax: 313-761-1208
(313) 665-0651

GelmanSciences

October 3, 1996

Attn: Ms. Evelyn R. Matson
NRC
Nuclear Materials Licensing Branch
Region III
Lisle, Il 60532-4351

Dear Evelyn:

Enclosed is our ammended application for materail license and responses to the items listed in your letter regarding the renewal of license number **21-26088-01**, control number **399364**. Please note that the individual who should be contacted regarding this application should be changed from Robert Blackburn to Michael S. Miller at (313) 665-0651. An updated copy of Gelman Sciences document number MP-06500-1 "Radioactive Materials Procedures" has been included with this packet and the relevent changes in the document have been listed in response to each item below. I have also included a copy of the Emergency Procedures which will be posted in the restricted areas, the sewer discharge log, and a map of the radioactive waste storage building.

Response to Item 1a: Section 3.2.2.4 of Gelman Sciences document number MP-06500-1 " Radio-Active Materials Procedures" has been revised to include a provision for a review of the program on a quarterly basis by the Vice President of Human Resources/Safety or whenever changes occur within the program. During these quarterly reviews the RSO will also update the VP of HR/Safety as to any changes in NRC regulations, the provisions of the license., and the compliance status of the program.

Response to Item 1b: The VP of HR/Safety will be responsible for reviewing the RSO's performance. This will be done on a annual basis, and be incorporated into the RSO's employee performance evaluation. The provisions for this are stated in section 3.2.2.5.

Response to Item 1c: Section 3.2.2.1 has been revised to include a quarterly review of the audits the RSO has conducted. These audits will include a review of the authorized users survey records, their safety procedures, and the area surveys which will be conducted by the RSO. These surveys will be documented and reviewed by the RSO and the VP of HR/Safety.

Response to Item 2: The individual originally named on the license renewal has resigned from that position. We have decided that rather than use an outside consultant RSO we will be naming Dr. Linda Belkowski as our RSO. Dr. Belkowski's training and experience as well as her resume is included in Item 7 of the NRC license renewal application enclosed with this letter.

Response to Item 3: The duties and responsibilities of the RSO are described in section 3.2 of MP-06500-1. These duties include: Review of proposed users and uses (3.2.1.1); annual and quarterly reviews of radiation safety program, occupational exposures, records of radiation surveys (3.2.2); and reviewing any instances of non-ALARA practices(3.2.3). Section 3.6 "Personnel Monitoring Program" outlines the circumstances in which all users would be required to wear personal monitoring equipment and the monitoring type. Section 3.8 "Rules for the Safe Use of Radioactive Materials" has been amended to include that all radioactive materials will be stored within the restricted area in a secured cabinet or freezer to prevent unauthorized removal of the materials (3.8.1.13).

Response to Item 4: Authorized Users have been specified in Item seven of the NRC application. Training and Experience sheets have been included in this section for each user.

Response to Item 5: Section 3.4.1 "Individuals Who Receive an Occupational Radiation Dose" has been revised to be consistent with 10 CFR 19.12.

Response to Item 6: A map of the waste storage facility has been inserted in Item 9 of the NRC Application. The radioactive waste storage facility is a detached, heated structure with doors that are locked on the off-hours (5:00 P.M. to 7:00 A.M.). The dimensions are 124' by 40'. The building has a fire detection system as well a fire suppression system. Other uses of the structure are for the storage of liquid hazardous waste, virgin chemicals, as well as excess stock from the warehousing operation. The radioactive materials storage area is a separate fenced in area that is marked and labeled with a "Caution Radioactive Material" and yellow/magenta tape. Section 3.13.4 describs how the waste area will be monitored.

Response to Item 7: Please find the attached Radioactive Emergency Spill Procedures sheet. In addition, Section 3.9 of MP-06500-1 outlines the procedures to be followed in the event of an emergency. A copy of these procedures will be posted in all areas in which radioactive material will be used or stored. Please note that the posted emergency procedures lists the name of the RSO, the RSO's ext. number, as well as a 24 hour pager number.

Response to Item 8: Sections 3.6.1 of MP- 06500-1 has been revised to indicate that all individuals who occupationally handle beta or gamma emitters will be issued whole body badges and individuals handling greater than one millicurie (stock vials) will be issued finger monitoring.

Response to Item 9: Section 3.12.1.5 has been amended to read "The trigger level for exposure rate surveys will be rates above 200 dpm/100 cm^2 for unrestricted areas or personal clothing and 2000 dpm/cm^2 for restricted areas, protective clothing worn only in restricted areas, or skin.". Section 3.12.1.6 has been amended to read that the trigger level for removable contamination surveys will be detection levels greater than the levels stated in 3.12.1.5 on repeat surveys.

Response to Item 10: Section 3.13.1.2 has been added to read that all materials to be disposed of via the sewer system must have a solubility greater than 0.003 moles/liter. A provision for keeping a sewer discharge log has been added to 3.13.1.1 to ensure that the monthly rate of disposal via the sewer does not exceed 1/10th of the values listed in 10 CFR 20 Appendix B table 3 (monthly concentrations) and that the yearly concentration for all nucleotides does not exceed 1 Ci. These values were obtained using the following formula:

$$\frac{\text{Table 3 Listed Conc. (uCi)}}{\text{mL}} \times \frac{1000\text{mL}}{\text{L}} \times \frac{2.7\times10^{6}\text{ L Water}}{\text{Month}} \times .10 = \textbf{Allowable Monthly Conc.}$$

Response to Item 11: Section 3.13.2 describes the procedures to be used to dispose of nucleotides with a half-life of 90 days or less. We will be allowing this material to decay on-site in our radioactive waste storage area. Monitoring of this facility will be done weekly, in a twenty foot radius from the storage area with a GM meter, and a four foot radius with smear tests. Records of this monitoring will be kept on site. 3.13.2.1 describes how we will be disposing of our Tritium waste (this is the only licensed material we will be receiving which has a half-life over 90 days, if other materials are added to the license in the future which have a half-life over 90 days specific disposal procedures will be added to ensure proper disposal). Chem-Nuclear in Barnwell S.C. has been contacted and has stated that we will be able to use them as our waste disposal site if and when the need arises.

If you have any further questions please feel free to contact me either via the phone at (313) 665-0651 or in writting at the address listed above.

Sincerely,

Gary Yezbick
Vice President Of Human Resources and Safety

Enclosure: Application for Material License; Emergency Spill Procedures; map of radioactive waste storage facility; sewer discharge log.

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

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)*
   - [ ] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [X] C. RENEWAL OF LICENSE NUMBER 21-26088-01

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

Gelman Sciences Inc.
600 S. Wagner Road
Ann Arbor, MI 48103-9019

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

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Robert Blackburn

TELEPHONE NUMBER
313-936-1582

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

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY
    AMOUNT ENCLOSED $ 1700

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
Human Resources Gary Yezbick, Vice President,	Gary Yezbick	4/4/96

FOR NRC USE ONLY

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

NRC APPLICATION

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ITEM 5

RADIOACTIVE MATERIAL

RADIONUCLIDE	CHEMICAL/PHYSICAL FORM	POSSESSION LIMIT
H-3	Amino Acids/Liquid	20 mCi
P-32	Nucleotides/Liquid	20 mCi
P-33	Nucleotides/Liquid	30 mCi
S-35	Nucleotides/Liquid	10 mCi
I-125	NaI/Liquid or Protein/Liquid	40 mCi
H-3	Solid and/or Liquid Waste	40 mCi
P-32	Solid and/or Liquid Waste	40 mCi
P-33	Solid and/or Liquid Waste	60 mCi
S-35	Solid and/or Liquid Waste	20 mCi
I-125	Solid and/or Liquid Waste	80 mCi

ITEM 6

PURPOSE(S) FOR WHICH

LICENSED MATERIAL WILL BE USED

a. See the following "Radioisotope Applicatic ·s at Gelman Sciences Inc."

b. For each radionuclide listed in ITEM 5, typical experiments will involve 1 mCi or less of activity. I-125 iodinations will be performed in the fume hood.

c. Licensed material will be used in the MAIN LABORATORY (Figure 1).

ITEM 6 (Continued)

RADIOISOTOPE APPLICATIONS AT

GELMAN SCIENCES INC.

Gelman Sciences Inc. (GSI) is a manufacturer of microporous membranes for industrial and laboratory use. Depending upon the nature of the application, GSI is able to provide microporous membranes which have either a low or high affinity for biomolecules (protein, drugs, nucleic acids). Hence, in addition to characterizing a membrane based on physical properties, our quality control operation also characterizes membranes based on binding capacity. GSI currently uses a dye binding test to evaluate binding capacity. Briefly, anionic and cationic dyes are passed through membranes and the resultant color is used as an indicator of the membrane's binding (charge) capacity. Unfortunately, dye-binding capacity does not always correlate with biomolecule-binding capacity.

Isotopes at GSI will be used as part of our quality control program to determine the binding capacity of microporous membranes. Isotopes will be used to "tag" proteins and nucleic acids. In one assay, radioactive biomolecules will be passed through membrane disks, washed and counted in a beta or gamma counter. The concentration of biomolecules bound to the membrane can be determined by knowledge of the specific activity of the preparation. In another assay, various radiolabeled molecules will be dotted onto membranes via a dot blot apparatus. The membranes will be washed and exposed to x-ray film to obtain a hard copy of radioactive spots. This assay will provide us with additional information on binding capacity but also provide information on the membrane's affinity and sensitivity.

Isotopes will also be used by GSI in application-oriented testing. Membranes designed for molecular biological research will be evaluated by most of the current techniques. These include Southern blots, Northern blots, plaque lifts and colony lifts. Hybridization with radiolabeled DNA probes will be performed to provide us with information on how a given lot of membrane can be expected to perform at the user level.

Lastly, isotopes will be used in experiments which GSI is requested to perform by customers. Occasions arise when customers desire the binding characteristics of a particular membrane for a given substance (drugs, growth factors). In such cases, radiolabeled substances will be purchased from authorized manufacturers and used in assays similar to those for binding capacity determinations. Briefly, the radiolabeled substance will be passed through membrane disks, washed and counted.

Item 7

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

Radiation Safety Officer:
Dr. Linda Belkowski will function as Gelman Sciences RSO. Dr. Belkowski's experience and resume are attached.

Authorized Users:
Linda Belkowski and Kevin Seely will be designated as Authorized Users under Gelman Sciences NRC license. These individuals training and experience sheets have been included with this application.

LINDA S. BELKOWSKI

4446 Ravinewood Drive
Commerce Township, MI 48382
810-685-7562

Education: Douglass College, Rutgers University
New Brunswick, New Jersey
B.A. 1979 - Biological Sciences (with honors)

Cornell University
Graduate School of Medical Sciences
Sloan-Kettering Division
New York, New York
Ph.D. 1986 - Molecular Biology and Virology

Professional Experience:

Senior Applications Specialist, Gelman Sciences, Ann Arbor MI September 1994 - August 1995 (Product and Technology Development Group) and August 1995 - present (Biopharm SBT)

Developed application protocols, technical literature and quality control test procedures for new laboratory and biotechnology products and coordinated beta site testing of these products prior to launch. Conducted evaluations of prototype new products and competitor products. Provided technical support to sales/marketing through in house testing, generation of internal literature and review of competitive literature, training sessions and discussions with customers at scientific meetings. Assited in customer support activities (trouble shooting, product selection, product perfromance questions) in technical services. Participated in marketing activities at trade shows.

Staff Scientist, Pall Corporation Scientific and Laboratory Services (Health Care Group), Glen Cove NY June 1990 - July 1994

Supervised laboratory and field projects involving applications of existing products (transfusion, intravenous, extracorporeal and breathing circuit filters, microporous membrane) as well as the development of new products and applications. Designed and evaluated new test apparatus for use in filter testing. Served as a team leader and coordinated work at customer sites leading to the development of a virus retentive filter for the biopharmaceutical industry. Provided technical input for the development of marketing plans for new and existing products. Through extensive customer interaction, defined performance requirements for new products and improvements to existing ones. Prepared technical reports for use by sales and marketing. Gave technical

presentations (oral, posters) at conferences as well as during customer visits. Established and supervised work in a tissue culture and flow cytometry facility for investigations in platelet biology, human bone marrow, leukocyte phenotyping and product biocompatibility. Served as an advisor to the departmental Health & Safety workgroup on issues dealing with biological or biohazardous materials.

Presented papers on the "Use of Microfiltration for the Removal of Viruses from Biopharmaceuticals" at the following conferences:

Annual Meeting of the Parenteral Drug Association, New Brunswick, NJ January 1991
International Biotechnology Exposition, San Francisco, CA October 1991
Annual Winter Meeting of the American Society of Mechanical Engineers (Bioprocess division), Anaheim, CA November 1992

Postdoctoral Fellow, Howard Hughes Medical Research Institute. Albert Einstein College of Medicine (with Dr. Barry Bloom), Bronx NY June 1986-June 1990

Investigated Regulatory Pathways in macrophage activation using a murine macrophage-like cell line as a model system. Generated mutants of this cell line to analyze specific steps in the activation process using biochemical and molecular biological techniques.

Predoctoral Fellow, Sloan-Kettering Institute for Cancer Research (with Dr. Ganes Sen), New York NY January 1982-May 1986

Studied the biochemical mechanism of the inhibition of virus replication by interferons. Developed analytical techniques to measure viral protein and nucleic acid synthesis in a cell culture system.

Publications:

Goldberg, M., Belkowski, L.S. and Bloom, B.R. (1990) Regulation of macrophage function by interferon-gamma: Somatic cell genetic approaches in murine macrophage cell lines to mechanisms of growth inhibition, the oxidative burst, and expression of the chronic granulomatous disease gene. J. Clin. Invest. **85**:563-569

Belkowski, L.S., Goldberg, M. and Bloom, B.R. (1989) Regulation of murine macrophage oxidative burst variants by interferon-gamma. The Biology of the Interferon System 1988. Y. Kawade and S. Kobayashi, eds. pp. 441-445

Belkowski, L.S., Fan, X-d. and Bloom, B.R. (1989) Transfection of murine and human macrophage-like cell lines by cationic liposomes. FOCUS **11**:35

Goldberg, M., Belkowski, L.S. and Bloom, B.R. (1989) Regulation of macrophage growth and antiviral activity by interferon-gamma. J. Cell Biology **109**:1331-1340

Belkowski, L.S. and Sen, G.C. (1987) Inhibition of vesicular stomatitis viral mRNA synthesis by interferons. J. Virol. **61**:653-660

Belkowski, L.S. (1986) Interferon-mediated inhibition of vesicular stomatitis virus

replication in cell variants with differential interferon sensitivities. Ph.D. thesis, Cornell University

Sen, G.C., Belkowski, L.S. and Kusari, J. (1985) Analysis of interferon actions using partially resistant cell variants. In: The 2-5A System: Molecular and Clinical Aspects of the Interferon-Regulated 2-5A System. New York: Alan R. Liss. pp. 175-182

Abstracts/Presentations:

Belkowski, L.S., Goldberg, M. and Bloom, B.R. Regulation of the respiratory burst in murine macrophage variants: an in vitro model for a human genetic disorder. UCLA Symposium on Molecular Biology. Lake Tahoe, February 1989.

Abstracts/Presentations:

Belkowski, L.S., Goldberg, M. and Bloom, B.R. Regulation of murine macrophage oxidative burst variants by interferon-gamma. Annual Meeting of the International Society for Interferon Research. Kyoto, Japan, November 1988.

Belkowski, L.S. and Sen, G.C. Analysis of the anti-vesicular stomatitis virus effect of interferon using cell lines with differential interferon sensitivities. Schering-UCLA Symposium on Molecular Biology. Steamboat Springs, April 1986

Sen, G.C., Belkowski, L.S. and Kusari, J. Analysis of interferon actions using partially resistant cell variants. Sixth Annual International Symposium on the 2-5A System. Toronto, June 1985.

Belkowski, L.S. and Sen, G.C. Effect of interferon on vesicular stomatitis virus replication in interferon-sensitive and -resistant cells. Fourth Annual Meeting of the American Society for Virology. Albuquerque, July 1985

Honors:

New Jersey State Scholarship, 1975-1977
James Nelson Fellowship (Douglass College Associate Alumnae), 1979
Frank L. Horsfall Award for Academic Achievement
(Cornell University), 1982

Professional Society Memberships:

Parenteral Drug Association
American Society for Microbiology

References: available upon request

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
LINDA BELKOWSKI	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION	Radiation Safety Course @ Rutgers Univ. June, 1979	8	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Radiation Safety Course @ Albert Einstein College of Medicine, Jan-March 1988	20	
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
^{125}I, ^{14}C, ^{3}H, ^{35}S, ^{32}P, ^{51}Cr	up to 30mCi ^{32}P, <1mCi for all others	Sloan Kettering Inst of Cancer Res.	>1000	^{32}P in vitro labelling, Binding Assays, Hybridizations, ^{3}H Thymidine Incorp., Protein/DNA Labelling
		Albert Einstein Coll. of Medicine	>1000	
~~^{125}I~~ ^{125}I	<0.5	Pall Corporation	~50	Radioimmunoassays

Linda & Jane -- Please fill in the form as soon as possible and send to Mitch Ehrlich ASAP. -- Vikas Padhye

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Kevin Seeley	

3 CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	Semester of Radiation Safety & Public Health @ Utah State University Fall 1986	45 hr	10 hr
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	(Training covered all 4 areas)		
d. RADIATION BIOLOGY	Also Radiation Safety @ UC Berkeley	4 hr	
e. RADIOPHARMACEUTICAL CHEMISTRY	None		

5. EXPERIENCE WITH RADIATION *(Actual use of Radioisotopes or Equivalent Experience)*

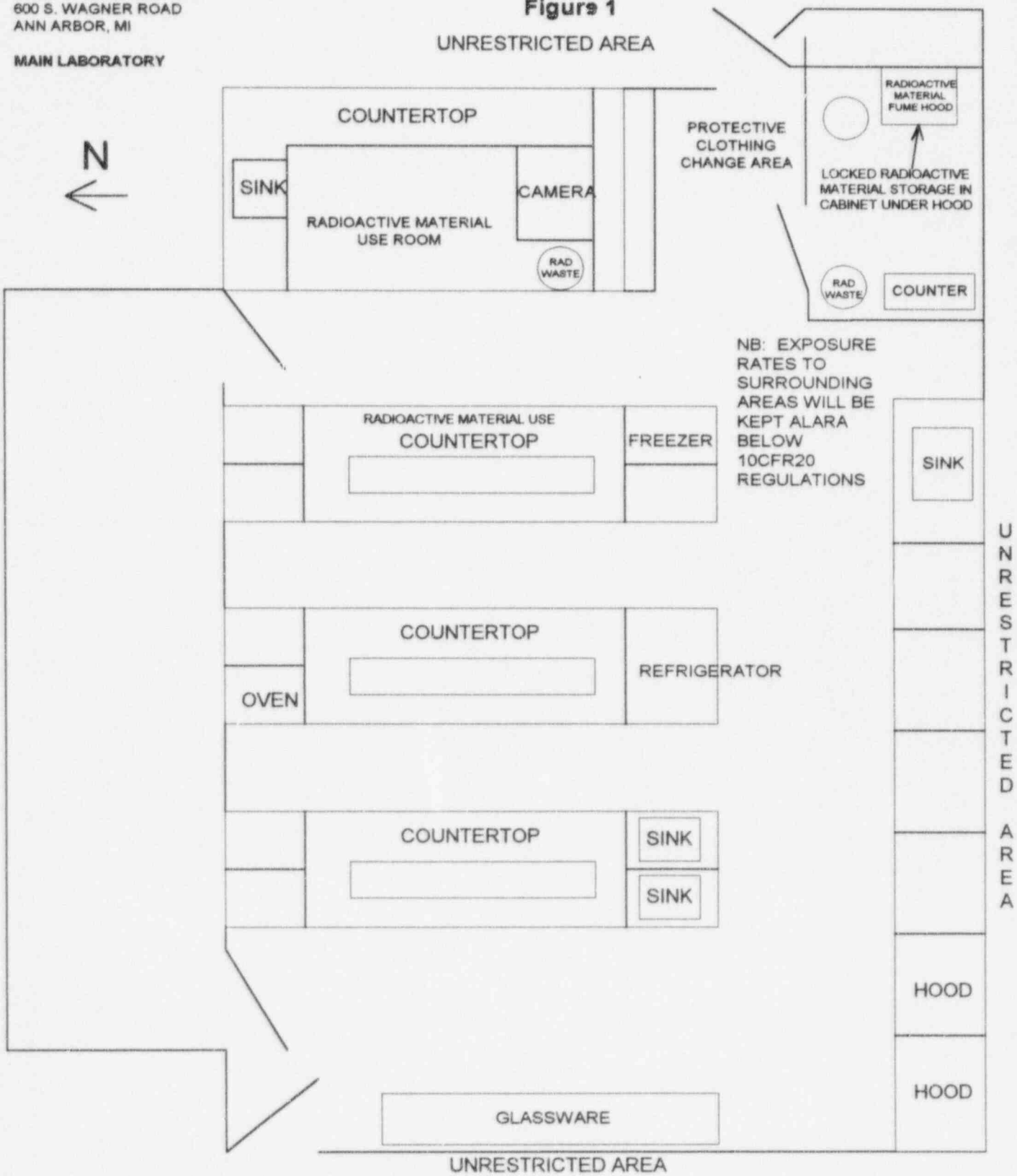
ISOTOPE	≤1 USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
^{35}S	1.0	Utah State University	1500	-labelled protein Synthesis
^{45}Ca	< 1.0	" "	200	-uptake
^{32}P	1.0	Iowa State University	3000	-probes
"	1.0	UC - Berkeley	3500	-sequencing " "

GELMAN SCIENCES INC.
600 S. WAGNER ROAD
ANN ARBOR, MI

MAIN LABORATORY

ITEM 9 **FACILITIES AND EQUIPMENT**

Figure 1



ITEM 9 (CONTINUED)

FACILITIES AND EQUIPMENT

a. Survey Equipment

Eberline E-120 with HP-260 thin window "Pancake" G.M. probe and attached lamp mantle check source.

b. Counting Equipment

Pharmacia Model 1209 Liquid Scintillation Counter.

c. Contamination Control

Absorbent paper or pads
Disposable Gloves
Fume Hood (for I-125 use)
Laboratory Coats
Shoe/Foot Covers
Shaving Cream or equivalent radiation decontamination foam
Radiation Decontamination Liquid
Soft Finger Scrub Brush

d. Remote Handling

Remote Pipettes
Remote Handling Tongs
Syringes

e. Shielding

Lead
Lead "pigs"
Lucite face-shield (for P-32 use)

Item 10

RADIATION SAFETY PROGRAM

See attached Gelman Sciences Inc. document number MP-06500-1

Item 11

WASTE MANAGEMENT

See section 3.13 of attached Gelman Sciences Inc. document number MP-06500-1

1.0 PURPOSE:

To provide for the purchase, receipt, storage, safe use, and disposal of radioactive material.

2.0 SCOPE:

All radionuclides used in applications in the main laboratory at Gelman Sciences, Ann Arbor office.

3.0 PROCEDURE:

3.1 Personnel Training Program

3.1.1 All individuals working in or frequenting a restricted area and who are likely to receive a dose in excess of 100 mrems per year will be instructed:

3.1.1.1 During initial orientation before assuming duties with, or in the vicinity of, radioactive materials.

3.1.1.2 During annual refresher training.

3.1.1.3 Whenever there is a significant change in duties, regulations, or in the terms of the license.

3.1.2 Instructions will be in verbal and written form and will include the following subjects:

3.1.2.1 Applicable regulations and license conditions.

3.1.2.2 Areas where radioactive material is used or stored.

3.1.2.3 Potential hazards associated with radioactive material in each area where the employees will work.

3.1.2.4 Appropriate radiation safety procedures.

3.1.2.5 The licensee's in-house work rules.

3.1.2.6 Each individual's obligation to report unsafe conditions to the Radiation Safety Officer (RSO).

3.1.2.7 Appropriate response to emergencies or unsafe conditions.

3.1.2.8 The worker's right to be informed of occupational radiation exposure and bioassay results.

3.1.2.9 Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

3.1.3 Successful completion of the training program will be based on: (1) the opinion of the RSO that the trainee is qualified to use radioactive materials and (2) a score of 80% or more on a written examination which will be sent to the department director for retention (Ref. QSR-02240-5 and DF-05350-1).A copy shall also be forwarded to Human Resources for retention in the employee's personnel file.

3.1.4 The RSO will schedule briefings and educational sessions to inform workers of As Low As is Reasonably Achievable (ALARA) program efforts.

3.1.5 The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

3.2 Radiation Safety Officer

3.2.1 Review of Proposed Users and Uses

3.2.1.1 The RSO will thoroughly review the qualifications of each proposed user with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

3.2.1.2 When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposures ALARA.

3.2.1.3 The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigation levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigation levels are exceeded.

Table I: Investigation Levels

	Body Part Exposed	Level I (mrems per calendar quarter)	Level II (mrems per calendar quarter)
1.	Whole body; head and trunk; active blood forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body	750	2250

3.2.2 Annual and Quarterly Review

3.2.2.1 Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis. This review will include going over the previous years audits to ensure compliance with NRC requirements, review of the users inventory and survey records, evaluation of the users safety procedures, and an independent work area survey (to be performed by the RSO).

3.2.2.2 Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 3.5 of this program and will prepare a summary report for management.

3.2.2.3 Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for management.

3.2.2.4 Quarterly review with management The radiation safety program will be reviewed quarterly with the RSO and the Vice President of Human Resources and Safety. This review will include updates or changes in NRC policies and regulations, the provisions of the license, and the compliance status of the program.

3.2.2.5 Annual review of RSO: The VP of HR and Safety will review the performance of the RSO on an annual basis. The results of this review will be kept in the RSO's personnel file.

3.2.3 Reviewing Instances of deviation from Good ALARA Practices

3.2.3.1 The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will attempt to determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3.3 Authorized Users

3.3.1 New Methods of Use Involving Potential Radiation Doses

3.3.1.1 The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.

3.3.1.2 The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

3.3.2 Authorized User's responsibility to Supervised Individuals

3.3.2.1 The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

3.3.2.2 The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

3.4 Individuals Who Receive Occupational Radiation Doses:

3.4.1 All individuals working in or frequenting a restricted area and who are likely to receive in excess of 100 mrens per year will be considered to be occupationally exposed.

3.4.2 Occupationally exposed workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

3.4.3 Occupationally exposed workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

3.5 Establishment of Investigation Levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigation levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigation levels that we have adopted are listed in Table I. These levels apply to the exposure of individual workers.

The RSO will review and record on form NRC-5, "Current Occupational External radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 20.401 of 10 CFR Part 20. The following actions will be taken at the investigation levels as stated in Table I:

3.5.1 Personnel dose less than Investigation Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table I values for the Investigation Level I.

3.5.2 Personnel dose equal to or greater than Investigation Level I but less than Investigation Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigation Level I and will report the results of the reviews to the individual and to management following the quarter when the dose was recorded. If the dose does not equal or exceed Investigation Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

3.5.3 Personnel dose equal to or greater than Investigation Level II

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigation Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's form NRC -5 or its equivalent will be presented to the management upon completion of the investigation.

3.5.4 Re-establishment of Investigation Levels to Levels Above Those Listed in Table I

In cases where a worker or group of workers' doses need to exceed an investigation level, a new, higher investigation level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented. The RSO will review the justification for and must approve or disapprove all revisions of investigation levels.

3.6 Personnel Monitoring Program

3.6.1 All individuals who are occupationally exposed to beta or gamma emitters other than H-3 or C-14 will be issued whole body badges, and individuals handling greater than one millicurie (stock vials) will be issued finger monitoring devices.

3.6.2 Other individuals who are exposed to radiation on an occasional basis such as loading dock, housekeeping, and security personnel, will not normally be issued exposure monitors.

3.6.3 External thyroid bioassays will be performed in accordance with *Regulatory Guide 8.20 "Application of Bioassay for I-125 and I-131."* Processes involving I-125 will be performed within a fume hood.

3.6.4 Whole-body film badges and TLD finger rings will be purchased from Landauer or some other vendor accredited by the National Institute of Standards and Technology. The badges will be changed out on a monthly basis by the individual user, the RSO, or his designate, and the reports supplied filed by the RSO. A photocopy of the most current report (minus personal information) will be posted in the laboratory and the original will be filed in the Radiation Safety Officer's files.

3.7 Survey Meter Calibration and Check

3.7.1 All survey instruments will be calibrated every six months and checked using a check source before each use. Survey instruments will be calibrated in accordance with Reg. Guide 10.8, Appendix B by:

3.7.1.1 The manufacturer.

3.7.1.2 GTS Instrument Services (NRC License No. 37-28097-01, Exp. 11/30/98)

3.7.1.3 Medical Physics Consultants (NRC License No. 21-2015301).

3.7.1.4 Any licensee authorized to perform survey meter calibrations as a service.

3.8 Rules for the Safe Use of Radioactive Materials

3.8.1 The RSO will ensure that authorized users, workers and ancillary personnel will:

3.8.1.1 Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

3.8.1.2 Wear disposable gloves at all times while handling radioactive materials.

3.8.1.3 Either after each procedure or before leaving the area, monitor hands and clothing for contamination in a low background area with GM. survey meter.

3.8.1.4 Not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.

3.8.1.5 Not store food, drink, or personal effects in areas where radioactive material is used or stored.

3.8.1.6 Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices in the designated low-background area.

3.8.1.7 Wear assigned extremity exposure monitoring device when handling radioactive materials, where required by 3.6.2.

3.8.1.8 Dispose of radioactive waste only in designated, labeled, and proper receptacles.

3.8.1.9 Never pipette by mouth.

3.8.1.10 Confine radioactive solutions in shielded containers that are clearly labeled per 10CFR20.

3.8.1.11 Always confine I-125 work to the fume hood.

3.8.1.12 The area utilized for radiation shall always be cleaned after use.

3.8.1.13 Store radioactive materials not being used in a secured, labeled, and designated cabinet or freezer to prevent unauthorized removal of the materials.

3.9 Emergency Procedures

3.9.1 Radioactive spills:

3.9.1.1 Don't panic! Get control of the situation. It is not a life or death situation.

3.9.1.2 Attend to personnel injuries or emergencies first. Injuries take precedence over radioactive contamination.

3.9.1.3 **WARN OTHERS** and request radiological assistance from others.

3.9.1.4 Direct potentially contaminated personnel to stay in a **CONTROLLED AREA** of the laboratory until they have been monitored and shown to be free of contamination.

3.9.1.5 **ISOLATE AND CONTAIN** the spill to a localized area of the laboratory. Post or tape off the affected area and establish an entry "control point" into the area. Lock the door to prevent entry if necessary.

3.9.1.6 **DO NOT SPREAD CONTAMINATION** beyond the immediate area. Leave contaminated shoes in the affected area.

3.9.1.7 **DO NOT** allow others into the contaminated area.

3.9.1.8 **MONITOR YOURSELF** and the affected area to identify the extent of the contamination. Use smears/swipes or an appropriate radiation survey meter. [REMEMBER: Radiation survey meters **cannot** detect tritium (H-3)!]

3.9.1.9 Contact the RSO as soon as possible for assistance. The RSO will supervise the cleanup of the spill and complete the radioactive spill report.

3.9.1.10 Initiate decontamination of any contaminated skin (soap and warm water). If contamination remains, induce perspiration by covering the area with plastic or rubber gloves and use foam hand cleaner or equivalent.

3.9.1.11 Wear appropriate protective clothing as required: long-sleeve lab coat, disposable gloves. shoe covers or booties, and safety goggles.

3.9.1.12 Cover **WET SPILLS** with paper towels or absorbent pads. Discard contaminated absorbent materials into a solid radioactive waste drum or plastic bag.

3.9.1.13 Cover **DRY SPILLS** with slightly dampened paper towels or absorbent pads.

3.9.1.14 Cleanup: Use disposable gloves and remote handling tools when possible.

3.9.1.15 Survey: Survey the area with a low-range GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

3.10 Package Order and Receipt Procedures

3.10.1 The RSO or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

3.10.2 The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

3.10.2.1 Written records will be made that identify the date received, authorized user, isotope, chemical form, activity, and supplier.

3.10.2.2 The above records will be checked to confirm that material received was ordered through proper channels.

3.10.3 All deliveries will be made during normal working hours. Radioactive packages will be delivered to the approved user or designee at the approved laboratory of use.

3.11 Procedure for Opening Packages Containing Radioactive Material

3.11.1 The RSO or designee will ensure that personnel open packages containing radioactive material as follows:

3.11.1.1 Put on gloves to prevent hand contamination.

3.11.1.2 Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3.11.1.3 Measure the exposure rate from the package at 1 meter (Transport Index, T.I.) and at the package surface. If the rate is significantly higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour (mrem/hr). Packages with the "White I" labels should be ≤0.5 mrem/hr at the package surface. Packages with the "Yellow II" labels should be ≤ 50 mrem/hr at the package surface.

3.11.1.4 Wipe the external package and remove the wipe sample to a low-background area. Assay the wipe with the thin-end window GM meter (liquid scintillation counter for H-3) to determine if there is any removable activity. If there is any contamination, notify the RSO.

3.11.1.5 Follow the steps listed below when opening the package:

- Remove the packing slip.
- Open the outer package following the supplier's instructions, if available.
- Open the inner package and verify that the contents agree with the packing slip.
- Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
- If anything unusual is noticed, stop and notify the RSO.

3.11.1.6 Verify that the material received is the material ordered.

3.11.1.7 Monitor the packaging material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding or recycling.

3.11.1.8 Record the receipt and all readings taken.

3.12 Area Survey Procedures

3.12.1 Surveys for contamination and ambient exposure rates will be performed as follows:

3.12.1.1 All areas where radioactive materials are used will be surveyed for ambient radiation exposure rates on each day of use and swipe tested for contamination each week of use. Area surveys will be performed with the GM survey meter and swipes counted on the liquid scintillation counter calibrated to read in dpm.

3.12.1.2 All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

3.12.1.3 Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h.

3.12.1.4 Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 200 dpm.

3.12.1.5 The trigger level for exposure rate surveys will be rates above 200 dpm/cm^2 for unrestricted areas or personal clothing, and 2000 dpm/cm^2 for restricted areas, personal clothing, or the skin.

3.12.1.6 The trigger level for removable contamination surveys will be the detection of values greater than the values listed in 3.12.1.5 on repeat surveys.

3.12.1.7 Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

3.12.1.8 A record shall be kept of all survey results on Swipes Test Record, DF-05350-4. The record will include:

- Location, date and type of equipment used.
- Initials of the person conducting the survey.
- Drawing of the area surveyed.

- Trigger levels keyed to the location on the drawing.
- Results keyed to the location on the drawing.
- Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

3.12.1.9 The RSO or designee will review the survey results on a quarterly basis for conformance to certain action levels.

3.13 Waste Disposal

3.13.1 Radioactive materials, in the form of liquids, solids and vials, will be disposed of into clearly marked drums in the biotechnology laboratory.

3.13.1.1 Liquid radioactive waste may be disposed of into the sanitary sewer system at a rate not to exceed 1/10 of the limits of Table III of Appendix B of 10 CFR 20. Records will be kept of the date, radionuclide, estimated activity released, estimated concentration, and site of release. This mode of disposal will be in addition to those stated in 3.13.1.

3.13.1.2 Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20.303. A check for normal water solubility must be made prior to the substance being sent into the sewer system. Substances with a solubility of 0.003 moles/liter or greater can be considered to be readily soluble, and disposed of in the sewer. Substances with a solubility lower than 0.003 mole/liter must be disposed of as specified in 3.13.1.3.

3.13.1.3 As necessary, the material shall be transferred to a sealed 55 gallon drum, sealed by designated personnel, and taken to the Radioactive Waste Storage Area. The material will be held there until the required holding period has elapsed.

3.13.2 Radioactive material with a half life less than 90 days (licensed materials P-32, P-33, S-35, and I-125) will be decayed for 10 half-lives in approved containers. The current storage sites for containers are the biotechnology laboratory (partially full containers) and the chemical storage building (full containers). Full waste containers will be removed to the chemical storage facility for decay. These containers will be clearly labeled as to radionuclide, date of last addition, and date when the material may be checked for disposal as non-radioactive waste.

3.13.2.1 Materials which are contaminated with or contain H-3 (tritium) should be stored in a separate waste container, used only for H-3 and sent to the chemical storage shed when full. When 3 drums of H-3 waste are collected in chemical storage shed they shall be sent off-site for waste disposal.

3.13.3 Prior to disposal, each container will be monitored as follows:

3.13.3.1 Low-range GM survey meter will be checked for proper operation.

3.13.3.2 Waste will be monitored in a low-level area.

3.13.3.3 Any shielding around the container will be removed.

3.13.3.4 All surfaces of each individual container will be monitored.

3.13.3.5 Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.

NOTE: Waste Management Inc. doesn't require defacing labels of waste to be incinerated.

3.13.4 Monitoring of Radioactive Waste Storage Area:

3.13.4.1 An area approximately 20 feet from the fence of the radioactive waste storage area will be measured weekly with a GM meter to assure that no contamination is present.

3.13.4.2 An area approximately 4 feet from the fence of the radioactive waste storage area will be smear tested in two to three places weekly to check for contamination. Levels above 200 dpm/cm^2 will be the trigger level for decontamination.

4.0 REFERENCE DOCUMENTATION:

4.1 QSR-02240-5, Training

4.2 DF-05350-1, Training Record

4.3 DF-05350-4, Swipes Test Record

4.4 U.S. N.R.C. Regulatory Guide 10.7

5.0 REVISION HISTORY:

Section(s) Changed	Changed By
3.6.2 deleted; 3.2.2.4-5, 3.4.1, 3.13.4-3.13.4.2 added; 3.1.1, 3.2.2.1, 3.4.2-3, 3.6.1-2, 3.8.1.1.13, 3.12.1.5-6, 3.13.1.1-2, 3.13.2-3.13.2.1	M. Miller
/replaces MP-05350-03	H. Distelzweig

EMERGENCY PROCEDURES FOR RADIOACTIVE MATERIAL SPILLS

STEP 1: Don't panic! Get control of the situation.

STEP 2: Att[illegible]ersonnel injuries first. Injuries take precede[illegible]adioactive [illegible]n. Warn others to evacuate the lab.

STEP 3: [illegible]ly contaminated personnel to stay in [illegible] been monitored and shown to b[illegible]

ST[illegible]he spill to a localized area [illegible]stablish an entry contro[illegible] [illegible]onnel into the conta[illegible]

[illegible]on beyond the [illegible]

[illegible]d the affe[illegible] to identi[illegible] or an a[illegible]ation sa[illegible] not det[illegible]

STEP 7: Contact the Radiation Sa[illegible]) as soon as possible for assistance. The RSO at Gelman Scienc[illegible]elkowski, ext. 6685. After normal business hours, the RSO pager number should be dialed. The pager number is 313-814-3815.

STEP 8: Initiate decontamin[illegible]kin with soap and water. If contamination rep[illegible]vering the area with plastic or rubber glove[illegible]alent.

STEP 9: Wear appro[illegible]red: long-sleeved lab coat, disp[illegible]goggles.

STEP 10: Cov[illegible]d contaminated ab[illegible]bag.

STEP 11: Cover dry [illegible]sorbent pads.

STEP 12: Survey the area with a low-range GM survey meter. Check the area around the spill, hands, clothing and shoes for contamination.

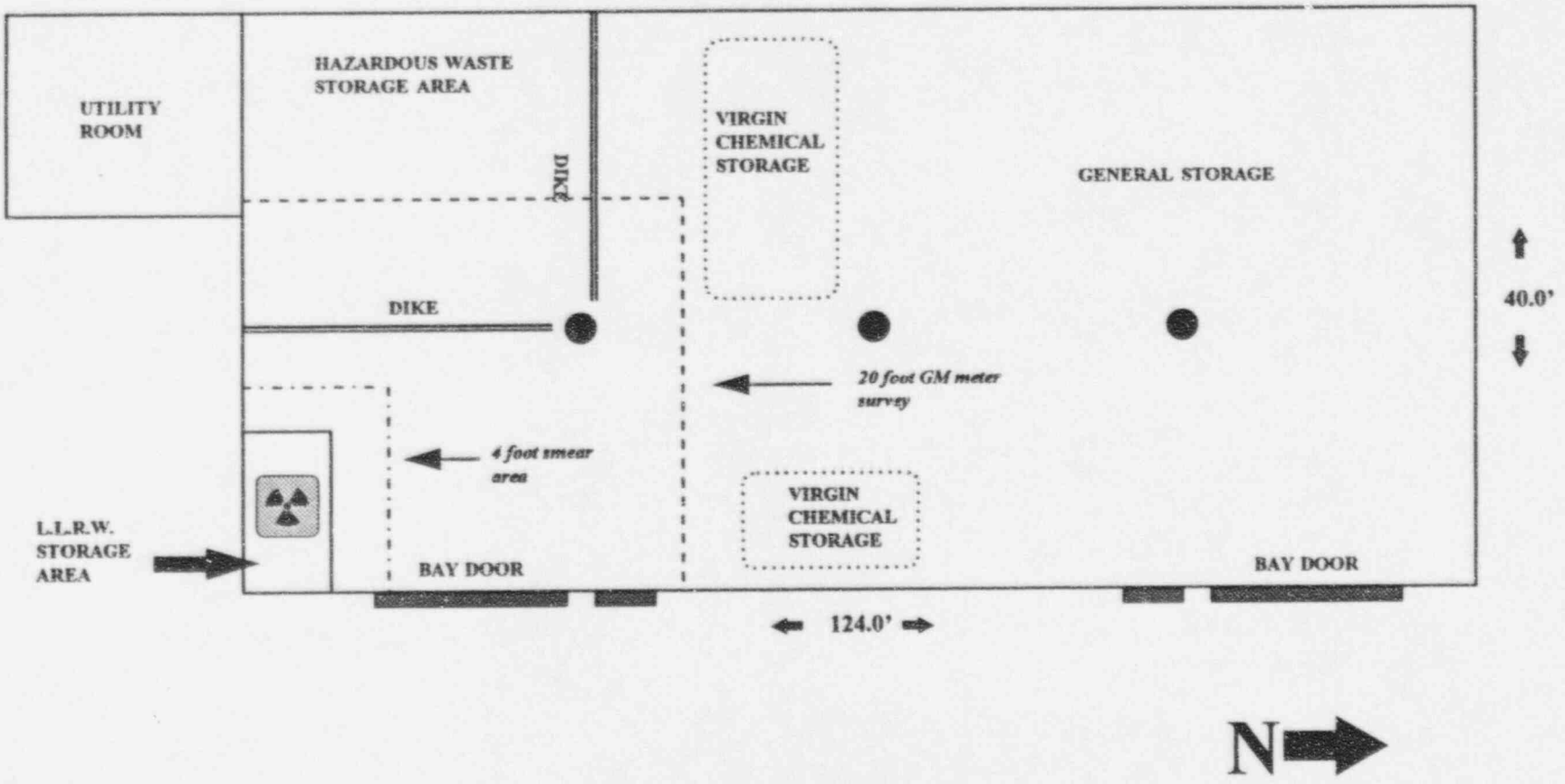
Linda Belkowski

Gelman Sciences RSO

Sewer Discharge Log

Approximate Concentrations

Date	User	H-3	Monthly Conc. Cannot Exceed .042 Ci/Month	P-32	Monthly Conc. Cannot Exceed .024 Ci	P-33	Monthly Conc. Cannot Exceed .216 Ci	S-35	Monthly Conc. Cannot Exceed .27 Ci	I-125	Monthly Conc. Cannot Exceed .005 Ci	Cumulative For the Year for all Substances Cannot Exceed 1 Ci/Yr.



FLOOR DRAINS - Three floor drains are located in the building. The floor is sloped to the drains to catch any spills or leaks. The drains lead to a 300 gallon under ground storage tank, located to the South of the building, which provides secondary containment for the entire building.

600 South Wagner Road
Ann Arbor, MI 48103-9019 USA
FAX (313) 913-6114
(313) 665-0651

GelmanSciences

August 22, 1996

Evelyn R. Matson
Health Physicist
Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Reference: License No. 21-26088-01
Docket No. 030-31413
Control No. 301258

Dear Ms. Matson,

We are in receipt of your letter dated August 2, 1996, requesting additional information in support of the renewal of our captioned license.

As you know, we have requested that consultant Robert Blackburn be named Radiation Safety Officer (RSO). Unfortunately, I received notice today that Mr. Blackburn will no longer be able to serve in this capacity. He has tendered his resignation from his consulting arrangement with us.

Therefore, please accept this letter as a request for a 30 day extension to respond to the information requested in your letter of August 2, 1996. With the resignation of our consultant, and our intentions at this time to name a Gelman Sciences full-time employee as RSO, some of the information you requested in this letter will no longer be relevant.

We expect that you will require us to amend item 7, Individual Responsible for Radiation Safety Program and their Training Experience, on our application for license renewal dated April 3, 1996. If other changes are required, please advise.

Your affirmative response to our request for an extension, as well as any additional information you may require at this time, would be greatly appreciated.

Sincerely,

Gary L. Yezbick/ds

Gary L. Yezbick
Vice President, Human Resources

PM: 8-28-96

RECEIVED
AUG 29 1996
REGION III
AUG 29 1996

AUG 0 2 1996

Gary Yezbick
Vice President
Gelman Sciences
600 South Wagner Road
Ann Arbor, MI 48103-9019

Dear Mr. Yezbick:

We have received your application dated April 4, 1996, requesting the renewal of License No. 21-26088-01. To complete the renewal process, please submit the following additional information about your radiation safety program:

1. 10 CFR 20.1101 requires that each licensee review their radiation protection program content and implementation at least annually. Therefore, please submit a description of your program for performing the required annual review. The annual audit procedures should include the following:

   a. A description of how senior management will become aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program. Senior management should be involved in reviewing the radiation protection program annually.

   b. A review of the Radiation Safety Officer's performance. Specific minimum qualifications should be established for an individual who will review the RSO's performance. Confirm that the results will be reported to senior management.

   c. A review of the audits that the RSO has conducted during the year. The review should determine that the RSO has audited authorized users' compliance with regulatory and NRC license requirements. The RSO's 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, etc. In addition, the review should examine the effectiveness and promptness for correcting deficiencies found by the RSO.

2. You have requested that a consultant be named Radiation Safety Officer (RSO) on your license. In support of this request, please address the following:

a. Describe the authority that will be delegated to allow the consultant-RSO to exercise authority over employee-authorized users when confronted with radiation safety problems that require corrective actions.

b. Describe how much time (hours per week) the consultant-RSO will spend in the performance of his RSO duties. The RSO's time commitment should be commensurate with the size, risk and scope of your licensed activities.

c. You should provide a commitment to the NRC that management will renegotiate the RSO's time commitment based on any evolving radiation safety program needs. In other words, if the program expands, the time commitment for the RSO must be reevaluated to assure that an adequate level of safety and compliance is maintained.

d. State that you will appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be given limited authority to assist the consultant-RSO with implementation of the radiation safety program. Confirm that this person will be an authorized user named on the license or provide the name, training and experience of the person.

e. Describe the availability of the consultant-RSO to respond to questions or operational issues that may arise in the operation your radiation safety program.

f. Specify the maximum amount of time it will take the RSO to arrive at the facility in case of a radiological emergency, such as a spill, or other event that requires his presence.

3. Describe the duties and responsibilities of your Radiation Safety Officer. The typical duties of a Radiation Safety Officer are:

a. To assess radiological hazards, and to 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 when not in use.

e. To perform routine inspections including surveys 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.

4. Your application states that authorized users will be designated by the RSO. The NRC allows this level of flexibility only in special circumstances where the licensee has shown a history of frequent additions of users and extensive experience operating a licensed program. At this time, we decided that your radiation safety program does not appear to meet the criteria for authorizing the RSO to name users. Therefore, provide a resume of the training and experience of each person who will directly supervise the use of material or who will use material without supervision. The resume should include the type (on-the-job or formal course work), location, and duration of the training. Training should cover: (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, mathematics and calculations basic to the use and measurement of radioactivity, and (c) biological effects of radiation. The description of the use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. The form entitled "Training and Experience, Authorized User or Radiation Safety Officer" has been enclosed for your convenience.

Each proposed authorized user should meet the training and experience criteria described in 10 CFR Part 33.15(b).

5. Your application under Item 3.1, "Personnel Training Program" states that all occupationally exposed personnel will be instructed. However, 10 CFR 19.12 requires that personnel (authorized users, lab technicians, clerical, housekeeping, security, etc.) who during employment are likely to receive in a year an occupational dose in excess of 100 mrems must receive the training described in 10 CFR 19.12. Therefore, revise your procedures to indicate that your definition of an occupationally exposed individual is consistent with the requirements of 10 CFR 19.12.

6. Provide a complete description of the location and facilities used to store radioactive waste. Is the area in a separate building? Describe security, weather protection, fire detection and suppression, and other uses of the area.

7. 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.

d. Confirm that these procedures will be posted in areas where radioactive material is used.

Appendix J of Regulatory Guide 10.8 may be helpful in preparing your response and provides procedures that are acceptable to the NRC.

8. Item 3.6 of your application states that individuals who may receive greater than one-tenth of the permissible whole body limit will be issued personnel monitoring. You have requested millicurie quantities of gamma and beta emitting radionuclides for which there is significant potential for an occupational dose that exceeds 10% of the 10 CFR 20.1201 limits. Therefore, please describe how you will evaluate when an individual needs whole body and finger monitoring. Please keep in mind the diversity of radionuclides you requested and the diversity of quantities authorized by the license. Your evaluation must be consistent with the potential for using the maximum quantities on the license, not just the typical use scenario. Alternatively, you may indicate that individuals handling gamma and beta emitters other than H-3 and C-14, will be issued whole body badges and individuals handling greater than one millicurie (including stock vials) will be issued finger monitoring.

9. Items 3.12.1.5 and 3.12.1.6 of your application state that your trigger level for ambient dose rates and removable contamination surveys will be rates above the normal background reading for that area. Normal background readings are changeable levels and present a "moving target" and you have not defined the maximum "normal background" levels that will be considered acceptable. Therefore, please confirm that the RSO will review and approve, in writing, the trigger levels (i.e., normal background) for both ambient exposure rates and removable contamination for the areas of use and that his decisions will be based on the ALARA concept. Table N-1 of Regulatory Guide 10.8 contains a sample of action levels for surface contamination that are acceptable to the NRC.

10. Item 3.13.1.2 states that disposal into the sanitary sewerage system will be made according to 10 CFR 20.303. Please note that Part 20 was revised in its entirety and became effective on January 1, 1993. The new requirement, 10 CFR 20.2003(a)(1) states that a licensee may

discharge licensed material into sanitary sewerage if the material is readily soluble (or is readily dispersible biological material). Information Notice 94-07 (enclosed) provides methods for determining compliance with this requirement which are acceptable to the NRC.

Please review this Information Notice and provide specific information how you will assure that your releases to the sanitary sewerage system will meet the solubility criteria in 10 CFR 20.2003(a)(1). If you wish, you may say that you will use a method described in Information Notice 94-07. Otherwise, describe your alternative methodology including the models, calculations, analytical techniques, and quality control measurements and the records that will be maintained

In addition, provide calculations to show compliance with 10 CFR 20.2003(a)(2)(3)(4) and confirm that records will be maintained of all disposals made into the sanitary sewage system.

11. A commercial waste disposal site is accessible to NRC licensees in your area. Therefore, we will not authorize extended interim storage of radioactive waste at this time. You should plan to have your waste packaged and shipped to a waste broker as needed.

I will continue my review of your application when I receive this information. Please reply in duplicate, within 30 days, and refer to Control Number 301258.

If you have any questions or require clarification on any of the information stated herein, please contact me at (630) 829-9822.

Sincerely,

Original Signed By
Evelyn R. Matson
Health Physicist
Materials Licensing Branch

License No. 21-26088-01
Docket No. 030-31413

Enclosures: 1. Information Notice 94-07, Sewage Solubility
2. Form entitled "Training and Experience, Authorized User or Radiation Safety Officer"

DOCUMENT NAME: M:\03031413.DF6
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OFFICE	DRSS/RIII	N									
NAME	ERMATSON:jaw										
DATE	08/2/95										

OFFICIAL RECORD COPY

April 30, 1996

Mitchell L. Ehrlich
Radiation Safety Officer
Gelman Sciences
600 South Wagner Road
Ann Arbor, MI 48103-9019

SUBJECT: LICENSE RENEWAL APPLICATION

Dear Mr. Ehrlich:

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Branch

License No. 21-26088-01
Control No. 301258

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DATE	04/30/96							

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