NRC FORM 374 (7-94) U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

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

Licensee	
1. Proteome, Inc.	3. License Number 20-30315-01
2. 200 Cummings Center, Suite 425C Beverly, Massachusetts 01915	4. Expiration Date September 30, 2001
	5. Docket or Reference No. 030-34169

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. 50 millicuries
B. Carbon 14	B. Any	B. 25 millicuries
C. Phosphorus 32	C. Any	C. 25 millicuries
D. Phosphorus 33	D. Any	D. 25 millicuries
E. Sulfur 35	E. Any	E. 75 millicuries

9. Authorized use

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

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at 200 Cummings Center, Suite 425C, Beverly, Massachusetts.

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

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

11. A. Licensed material shall be used by, or under the supervision of, James I. Garrels, Ph.D.

B. The Radiation Safety Officer for this license is James I. Garrels, Ph.D.

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

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-30315-01

Docket or Reference Number: 030-34169

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

14. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

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

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

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

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive 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 May 31, 1996
    B. Letter dated August 1, 1996

Date SEP 19 1996

For the U.S. Nuclear Regulatory Commission

By Original Signed By:
Keith D. Brown, Ph.D

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

SEP 19 1996

License No. 20-30315-01
Docket No. 030-34169
Control No. 123297

James I. Garrels, Ph.D.
President
Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

Dear Dr. Garrels:

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

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

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

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

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

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

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

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

OFFICIAL RECORD COPY

ML 10

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

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

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

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

5. Request and obtain a license amendment before you:

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

b. change Radiation Safety Officer;

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

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

e. change ownership of your organization.

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

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

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

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

Thank you for your cooperation.

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

License Nr. 20-30315-01
Docket No. 030-34169
Control No. 123297

Enclosures:
1. License No. 20-30315-01
2. 10 CFR Parts 2, 19, 20, 30, 71, 170, and 171
3. NRC Forms 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L2030315.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Brown/kdb							
DATE	09/18/96		09/ /96		09/ /96		09/ /96	

OFFICIAL RECORD COPY

PROTEOME, INC.

200 Cummings Center, Suite 425C
Beverly, MA 01915
TEL: (508) 922-1643 FAX: (508) 922-3971
Email: jg@proteome.com WWW: www.proteome.com

MS 16
Q-7

August 1, 1996

Docket No. 030-34169
Control No. 123297

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Dr. Brown:

This letter is in reply to your letter of July 3, 1996 regarding our application dated May 31. I have addressed each of the issues as follows:

1. We have two proposed users of radioactive material in our company, myself and a research technician Erin Butler. My training and experience were outlined on the original application, and we have added pages for Ms. Butler. Ms. Butler was trained last year during summer employment at New England Biolabs Inc. The course she took was a 4 hr course given by Robert U. Johnson, who is also the radiation safety consultant for our company. The outline of the course she took is the same as the one outlined in our Radiation Safety Guide. Ms. Butler did not actually use radioactivity in her previous job. She will use radioactive materials under my supervision.

2. We have removed the mention of *in vivo* studies from our application. We do not plan any studies in animals.

3. We have changed Appendix 5 and 6 our our Radiation Safety Guide to address the points mentioned. Because of the use of millicurie amounts of some isotopes, we will perform weekly surveys. We verify that the results of these weekly surveys will be recorded and that surveys performed by users will also be recorded.

4. We confirm that records will be kept of disposal of material from the decay-in-storage program. A new paragraph has been added to our Radiation Safety Manual to establish this procedure.

5. We confirm that the contamination limit for phosphorus 33 will be 200 disintegrations per minute per 100 square centimeters. The Radiation Safety Guide has been amended to include this fact.

Amended copies of the application and Radiation Safety Guide are included. No changes have been made to the application or to the Guide other than those mentioned above.

I hope this information will allow you to complete your review. We will be happy to provide any other information that might be needed.

Sincerely,

James I. Garrels, President
Proteome, Inc.

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: 8 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)
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

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

Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James I. Garrels Ph.D.

TELEPHONE NUMBER

(508) 922-1643

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. See Attachment I
   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. See Attachment I

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. See Attachment III

9. FACILITIES AND EQUIPMENT. See Attachment IV

10. RADIATION SAFETY PROGRAM. See Attachment V

11. WASTE MANAGEMENT. See Attachment VI

12. LICENSING FEES (See 10 CFR 170 and Section 170.31)
    FEE CATEGORY 3M
    AMOUNT ENCLOSED $ $1400.

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
James I. Garrels Ph.D., President	James I. Garrels	5/31/96

FOR NRC USE ONLY

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

NRC FORM 313 (10-94) PRINTED ON RECYCLED PAPER

OFFICIAL RECORD COPY ML 10

12329 AUG - 2 1996

Attachment I

Item 5. Radioactive Material

Element and Mass No.	Chemical/Physical Form	Max Activity to be On Hand at Any One Time
Phosphorus-32	Organic and Inorganic Liquids (non-volatile)	25 mCi
Phosphorous-33	Organic and Inorganic Liquids (non-volatile)	25 mCi
Sulfur - 35	Organic and Inorganic Liquids (non-volatile)	75 mCi
Hydrogen - 3 (tritium)	Organic and Inorganic Liquids (non-volatile)	50 mCi
Carbon - 14	Organic Liquids (non-volatile)	25 mCi

Item 6. Use of Radionuclides

All radionuclides which Proteome, Inc. expects to use will be in microcurie and, occasionally, millicurie amounts. The basic nature of our research is such that radionuclides will be used in biochemical and microbiological studies for protein labeling. S-35, H-3 and C-14 will be used for *in vitro* protein labeling experiments. P-32 and P-33 may be used in millicuries amounts for labeling phosphorylated proteins.

The possession limits have been chosen to allow for storage of radiolabeled protein samples as reference samples for future research and to include the activity in Proteome's On Site Decay Storage Program. Review by the RSO will preclude any individual using more than required by experience and need.

Attachment II.

Item 7. Responsible Individuals (Curricula Vitae Included)

Radiation Safety Officer (RSO):	James I. Garrels Ph.D. President/Senior Scientist
Authorized Supervisors (AS)	James I. Garrels Ph.D.
Authorized User	Erin Butler, B.S.

Curriculum Vitae

James I. Garrels

Educational Experience

California Institute of Technology, Pasadena, CA	B.S.	1971	Biology and Physics
University of California, San Diego, CA	Ph.D.	1978	Biology

Professional Experience

Feb. 1995 - present	President, Proteome, Inc.
1993 - Feb, 1995	Visiting Scientist, Harvard Medical School, Boston, MA,
1985 - Jan, 1995	Senior Staff Scientist and Director of the QUEST Protein Database Center, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY.
1980 - 1985	Senior Staff Investigator, Cold Spring Harbor Laboratory.
1979 - 1980	Staff Investigator, Cold Spring Harbor Laboratory.
1978 - 1979	Postdoctoral Fellow, Cold Spring Harbor Laboratory.

Awards and Memberships

Tau Beta Fi
American Society for Cell Biology
American Society for Biochemistry and Molecular Biology
Genetics Society of America
American Society for Microbiology
American Electrophoresis Society
Scientific Advisory Board, Protein Databases Inc. (1983-1988)

Outside Activities

1983-1988	Consultant, Protein Databases Inc.
1988-1994	Consultant, Millipore Corporation.

Bibliography (of 59 total)

J.I. Garrels and W. Gibson (1976) Identification and characterization of multiple forms of actin Cell, **9:** 793-805.

T. Hunter and J.I. Garrels (1977) Characterization of the mRNAs for a, b, and g actin. Cell, **12:** 767-781.

J.I. Garrels (1979) Two-dimensional gel electrophoresis and computer analysis of proteins synthesized by clonal cell lines. J. Biol. Chem., **254:** 7961-7977.

J.I. Garrels and D. Schubert (1979) Modulation of protein synthesis by nerve growth factor. J. Biol. Chem., **254:** 7978-7985.

J.I. Garrels (1979) Changes in protein synthesis during myogenesis in a clonal cell line. Devel. Biol., **73:** 134-152.

J.I. Garrels, J.T. Farrar and C.B. Burwell IV (1984) The QUEST system for computer-analyzed two-dimensional electrophoresis of proteins., In: Two-dimensional Gel Electrophoresis: Methods and Application, (ed. J.E. Celis and R. Bravo), pp. 37-91, Academic Press, New York.

M.B. Mathews, R.M. Bernstein, B.R. Franza and J.I. Garrels (1984) Identity of the proliferating cell nuclear antigen and cyclin. Nature, **309:** 374-6.

J.I. Garrels (1989) The QUEST system for quantitative analysis of two-dimensional gels. J. Biol. Chem, **264:** 5269-5282.

J.I. Garrels and B.R. Franza Jr. (1989) The REF52 protein database: Methods of database construction and analysis using the QUEST system, and characterizations of protein patterns for proliferating and quiescent REF52 cell cultures. J. Biol. Chem., **264:** 5283-5298.

J.I. Garrels and B.R. Franza Jr. (1989) Transformation-sensitive and growth-related changes of protein synthesis in REF52 cells. J. Biol. Chem. **264:** 5299-5312.

M.E. Lambert, Z.A. Ronai, I.B. Weinstein and J.I. Garrels (1989) Enhancement of major histocompatibility class I protein synthesis by DNA damage in cultured human fibroblasts and keratinocytes. Mol. Cell. Biol., **9:** 847-850.

L. Mizzen, C. Chang, J.I. Garrels and W.J. Welch (1989) Identification, characterization, and purification of two mammalian stress proteins present in mitochondria: Grp75, a member of the Hsp70 family, and Hsp58, a homolog of the bacterial groEL protein. J. Biol. Chem, **264:** 20664-20675.

J.I. Garrels, B.R. Franza, C.Chang, and G.I. Latter (1990) Quantitative exploration of the REF52 protein database: Cluster analysis reveals the major protein expression profiles in responses to growth regulation, serum stimulation, and viral transformation. Electrophoresis, **11**: 1114-1130.

K.E. Latham, J.I. Garrels, C. Chang, and D. Solter (1991) Quantitative analysis of protein synthesis in mouse embryos I: Extensive reprogramming at the one- and two-cell stages. Development, **112**: 921-932.

K.E. Latham, J.I. Garrels, C. Chang, and D. Solter (1992) Analysis of embryonic mouse development: construction of a high-resolution, two-dimensional gel protein database. Appl. Theor. Electrophoresis, **2**: 163-170.

J.I. Garrels, B.R. Franza Jr., S.D. Patterson, K.E. Latham, D. Solter, C. Chang, and G.I. Latter (1992) Protein databases constructed by quantitative 2D gel electrophoresis and protein identification from 2D gels. J. Protein Chem. **11**, 394-395.

K.E. Latham, J.I. Garrels, and D. Solter (1993) Two-dimensional gel analysis of protein synthesis. Meth Enzymol. **225**: 473-488.

P.V. Hornbeck, J.I. Garrels, Y. Capetanaki, and S. Heimer (1993) Vimentin expression is differentially regulated by IL-2 and IL-4 in murine T cells. J. Immunol. **151**:4013-4021.

K.E. Latham, R.S.P. Beddington, D. Solter, and J.I. Garrels (1993) Quantitative analysis of protein synthesis in mouse embryos. II: Differentiation of endoderm, mesoderm, and ectoderm. Mol. Reprod. and Devel. **35**: 140-150.

J.I. Garrels, B.R. Franza, Jr., S.D. Patterson, K.E. Latham, D. Solter, C. Chang, and G.I. Latter (1993) Protein databases constructed by quantitative two-dimensional gel electrophoresis. In: Methods in Protein Sequence Analysis (K. Imahori and F. Sakiyama, Eds), p. 247-253.

P.J. Monardo, T.J. Boutell, J.I. Garrels, and G.I. Latter (1994) A distributed system for two-dimensional gel analysis. CABIOS, **10** 137-143.

S.D. Patterson and J.I. Garrels (1994) Two-dimensional gel analysis of posttranslational modifications. In: Cell Biology: A Laboratory Handbook, Vol. 3 (J. E. Celis, ed.), p. 249-257, Academic Press, NY.

K.E. Latham, J.I. Garrels, and D. Solter (1994) Alterations in protein synthesis following transplantation of mouse 8-cell stage nuclei into enucleated 1-cell embryos. Dev. Biol. 163:341-350 .

J.I. Garrels, B. Futcher, R. Kobayashi, G.I. Latter, B. Schwender, T. Volpe, J.R. Warner, and C.S. McLaughlin (1994) Protein identifications for a *Saccharomyces cerevisiae* protein database. Electrophoresis **15**:1466-1486.

G.I. Latter, T. Boutell, P.J. Monardo, R. Kobayashi, B. Futcher, C. McLaughlin, and J.I. Garrels (1995) A *Saccharomyces cerevisiae* Internet Protein Resource. Electrophoresis **16**:1170-1174.

J.I. Garrels (1995) YPD — A Database for the Proteins of *Saccharomyces cerevisiae* Nucleic Acids Res. **24**:46-49.

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Instructions. Complete this form and submit to Radiation Safety Officer. Authorization for use requires approval of Radiation Safety Officer.

Name of Applicant

James I Garrels Ph.D.

Social Security Number of Applicant

Department & Supervisor

Location where Isotopes will be used or stored

company wide

Radioactive material(s):

List chemical symbol and mass number of each	**Form of Material (Chemical and/or Physical)**
all isotopes	See Attachment I of application

Previous Training and Education

Subject Covered	On-Job Training Yes/No	Hours	Institution	Date Completed
Principles and Practices of Radiation Protection	Yes	2 hr. course	Salk Institute	1972
Measurement and Monitoring Techniques	Yes	2 hr. course	Calif. Institute of Technology	1970
Mathematical Principles for Calculating Activity	Yes	3 hr. course	Cold Spring Harbor Lab	1978
Biological Effects of Radiation	Yes	2 hr. course	Harvard	1992

Previous Experience (actual use of radioactive materials)

Isotope	Maximum Activity per experiment	Where Used	Duration of use	Type of Use
^{32}P	10 mci	Salk Inst., Cal Tech, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling
^{33}P	5 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	18 yrs.	Protein Labeling
^{35}S	10 mci	Salk Inst, Cal Tech, Cold Spring Harbor, Harvard	20 yrs.	Protein Labeling
^{3}H	10 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling
^{14}C	5 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling

Curriculum Vitae

Erin Butler

Educational Experience

Rensselaer Polytechnic Institute B.S. 1996 Biology

Professional Experience

June, 1996 - present	Research Technician, Proteome, Inc.
Summer, 1995	Internship, New England Biolabs, Beverly, MA

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Instructions. Complete this form and submit to Radiation Safety Officer. Authorization for use requires approval of Radiation Safety Officer.

Name of Applicant

Erin Butler

Social Security Number of Applicant

[redacted]

Department & Supervisor

James I. Garrels

Location where Isotopes will be used or stored

company wide

Radioactive material(s):

List chemical symbol and mass number of each	**Form of Material (Chemical and/or Physical)**
^{32}P, ^{33}P, ^{35}S, ^{3}H, ^{14}C	Organic and inorganic liquids (non-volatile)

Previous Training and Education

Subject Covered	On-Job Training Yes/No	Hours	Institution	Dated Completed
Principles and Practices of Radiation Protection, Measurement and Monitoring Techniques, Mathematical Principles for Calculating Activity, and Biological Effects of Radiation	Yes	4 hr. course	New England Biolabs	1995

Previous Experience (actual use of radioactive materials)

Isotope	Maximum Activity per experiment	Where Used	Duration of use	Type of Use

NONE

Attachment III.

Item 8. Training of Individuals Working in or Frequenting Radioactive Area

The Proteome, Inc. Radiation Safety Training Program is detailed in Appendix II of the Radiation Safety Manual. Training will be provided by our outside Radiation Safety Consultant, Mr. Robert U. Johnson, former Harvard University Associate Radiation Safety Officer. Training will include sessions for ancillary workers who work in rooms or on equipment that may contain radioactive material.

Attachment IV.

Item 9. Facilities and Equipment

Floor plans of the Proteome, Inc. facilities in Beverly, MA are attached. The laboratory areas in which radioisotopes will be used are indicated, as is the location of the receiving area and waste storage facility.

Features:

Floor covering:	Rolled seamless vinyl and vinyl tile or equivalent.
Working surfaces:	Stainless steel, Formica, epoxy coated stone or equivalent; absorbent, plastic-backed paper will be used at all times.
Hoods:	Impervious surfaces (epoxy, stainless steel, or equivalent); with minimum of 100 linear feet per minute air flow across the front of the hood opening with the hood sashes at normal height (see floor plan). The hood flow will be checked semiannually

Other:

Receiving	All shipments will be brought to the Receiving Area for check-in, radiation survey and logging.
Security	The laboratory facilities at Proteome, Inc. are locked whenever not occupied by trained personnel, and are always locked after hours and on weekends. The lab areas are segregated from the office areas and only authorized personnel are allowed into the laboratory where radioactivity is used. The rooms containing radioactive material are always locked when not in use. Waste storage areas are locked at all times.
Waste Storage:	Waste storage for both the Decay-in-Storage Plan and the storage of long-lived waste prior to shipping will be in a locked room within the inner laboratory where radioactivity is used. See the attached floor plan.

Attachment IV. (con'd)

Item 9. Radiation Detection Equipment and Calibration

Radiation Detection Equipment

1. Geiger-Mueller Survey Instruments (Quantity = 1). Additional units will be added as required.

Model:	Ludlum Model 3 with 44-9 Pancake Detector (Q=3)
Use:	Frisker for alpha, beta, gamma
Range:	0.025 to 200 mr/hr.
Check	Check source (1 μCi Cs-137)

Calibration Procedure

Instrument calibration is performed at least annually and following repair by Mr. Robert U. Johnson, Independent Consultant (and former Harvard University Associate Radiation Safety Officer) or at an NRC licensed calibration facility.

1. A calibration label is affixed to the instrument, specifying the ranges that have been calibrated and the date of calibration.

2. A certificate of calibration is provided for each instrument calibrated. Calibration certificates are kept at the company for a minimum of three years.

Attachment V.

Items 10. Radiation Protection Program

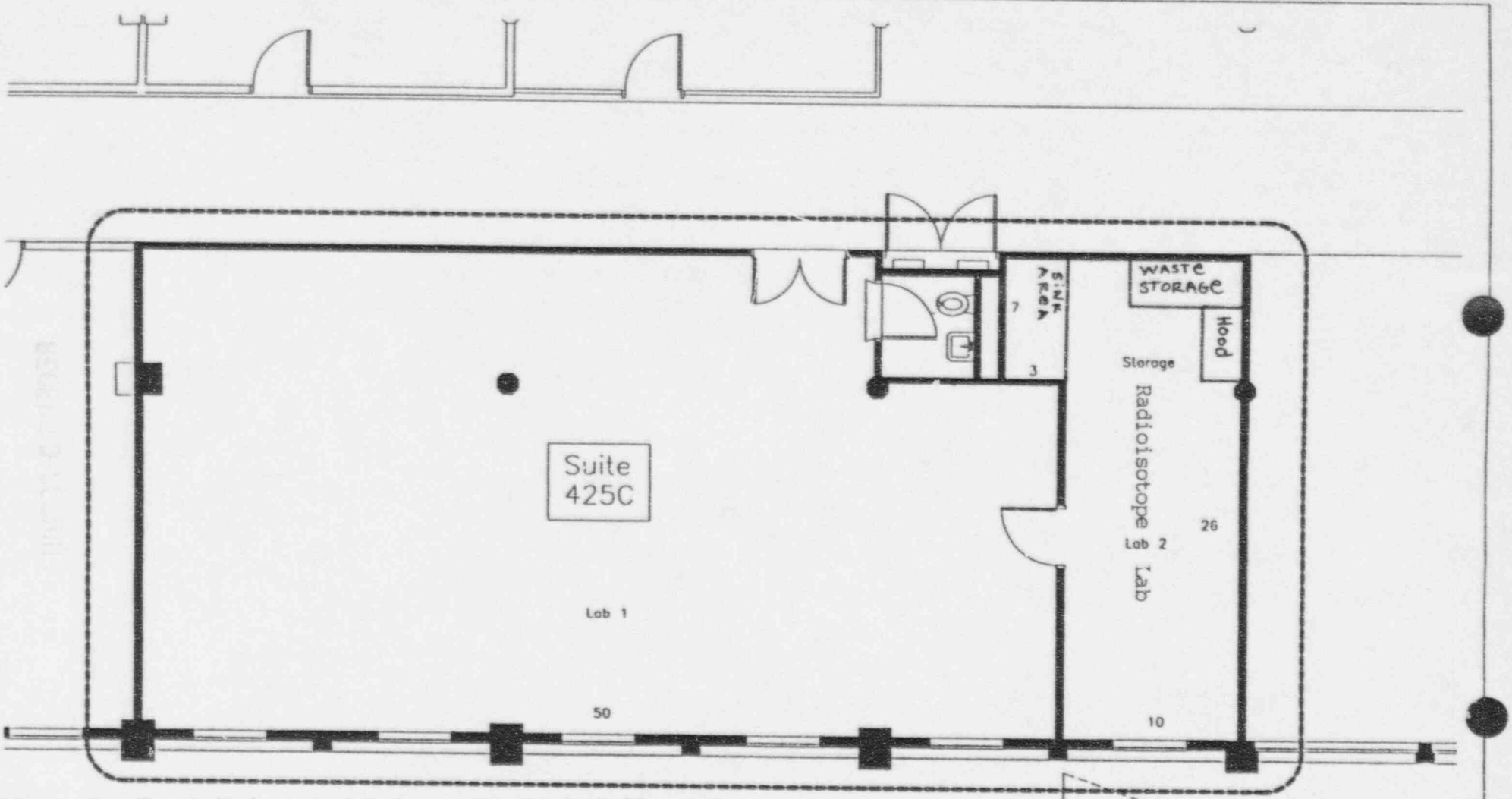
The attached Radiation Safety Guide covers all aspects of Proteome, Inc.'s Radiation Protection Program in detail. Please refer to the table of contents for specific items.

Attachment VI.

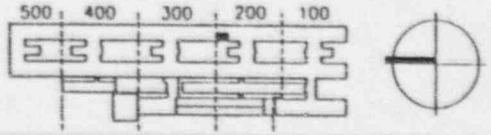
Item 11. Waste Management

The attached Radiation Safety Guide covers all aspects of Proteome, Inc.'s Waste Management Program. Please refer to Table of Contents for specific items.

Laboratory waste is collected and stored temporarily in metal containers within the laboratories. Periodically, waste is gathered, labeled by isotope, and moved to a secure Waste Storage Room for decay-in-storage and for holding of long-lived waste prior to shipping as described in the company fulfillment of Regulatory Guide 90.09. This room (see floor plan in Attachment IV) has a locked door and restricted access. It is surveyed weekly and the results logged.



Notes:
1. The Radioisotope Lab is a separate lockable room.
2. The hood in the Radioisotope Lab measures approximately 4 feet wide by 3 feet deep.
3. A sink for disposal of radioactive waste is in the Radioisotope Lab.
4. The waste storage area is a locked area within the Radioisotope Lab.
5. The holding area for new shipment of radioactive material is in the hood.



Cummings Properties

100 Cummings Center, Beverly, MA (508) 922-9000

Corporate Offices, 200 West Cummings Park, Woburn, MA 01801 (617) 933-8000

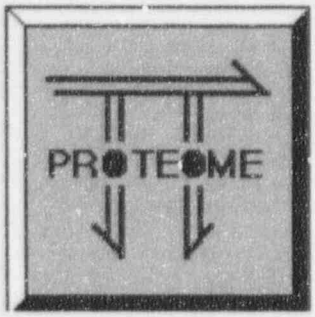
Lease Proposal Plan

Proteome, Inc.

200 Cummings Center, Suite 425C

L.S.F.: 1959
Date : 17 APR 96
Drawn: ARC
Scale: 1"=8'-0"
Revised:

- All dimensions are approximate.
- CPM standard construction unless otherwise noted.
- Furnishings are shown for illustrative purposes only.
- No representation is made as to the suitability of this design for Lessee's use or occupancy.



RADIATION SAFETY GUIDE

1996

TABLE OF CONTENTS

INTRODUCTION

All uses of radioactive material at Proteome, Inc. are controlled by the Radiation Protection Program.

> NO WORK WITH SOURCES OF IONIZING RADIATION MAY BE INITIATED UNTIL AUTHORIZATION HAS BEEN OBTAINED FROM THE RADIATION SAFETY OFFICER.

All used of ionizing radiation (except ultra-violet radiation) in Massachusetts are controlled and regulated by the U.S. Nuclear Regulatory Commission (NRC). Proteome, Inc. has established a Radiation Safety Program to give the necessary assurances to the NRC as well as to the company management that all potentially hazardous sources of radiation will be used safely. This guide describes the organization of the program and specifies the regulations, policies and procedures and practices which are to be followed when using radioactive materials.

It is Proteome, Inc. policy that use of radioactive materials be kept to a minimum and that there be no unwarranted radiation exposure. Due regard must always be given to the safety and welfare of the radiation workers and the general population, as well as to the protection of Proteome, Inc. property and liability. Proteome, Inc.'s operational policy places responsibility on the user and persons who supervise the use of radioactive materials. Supervisors will satisfy their responsibilities by adhering to this Radiation Safety Guide and by requesting assistance from the Radiation Safety Officer (RSO) when there are questions or suspected problems.

This guide is organized in the following manner:

Section 1	General description of the Proteome, Inc. Radiation Safety Program Organization and Responsibilities
Section 2	Summary of Policies and Procedures
Appendices	Detailed Procedures and Practices

1. Description of the Proteome, Inc. Radiation Safety Program

There are three levels of authority in the Radiation Safety program:

The Radiation Safety Officer (RSO)

The RSO together with the management of Proteome, Inc. establishes the Radiation Safety Policy such that:

1. Unwarranted radiation safety exposures of Proteome, Inc. employees and general public are avoided.

2. Compliance with all the federal and state regulations is assured.

3. Proteome, Inc.'s property and liability are protected.

Duties of the Radiation Safety Officer include:

a. Ensuring that each use of radioactive material is by or under the supervision of a properly authorized supervisor.

b. Enforcing the wearing of proper dosimetry, conducting surveys of all use and storage of radioactive materials and being sure that all areas, containers, and equipment are properly labelled. This would include control of exposures of pregnant females.

c. Assuring that radioactive material is properly secured against unauthorized removal when not in use.

d. Maintaining current working records of the receipt and disposition of radionuclides including use in research, waste disposal, transfer, storage, etc.

e. Evaluating the radiological hazards by routine inspections and ensuring the implementation of appropriate radiation safety precautions.

f. Avoiding any unnecessary exposures to him/herself and others under his/her supervision in accord with ALARA.

g. Keeping an inventory of radioactive materials on hand.

h. Responsibility of compliance with all regulations governing the use of radioactive materials.

i. Limiting the use of the radionuclides to quantities and for the purposes specified in the license.

j. Ensuring the training and indoctrination of all persons using radioactive materials and ensuring that workers are properly supervised.

The Authorized Supervisor (AS)

Senior Scientists or Department Managers have primary responsibility for the radiation safety associated with each source under their control. Each AS must ascertain that persons under their supervision using these sources are properly trained and aware of the attendant hazards. Each AS must also assure that use of the sources conform to all the safety conditions of this authorization and those of this Guide.

The Supervised User (SU)

These individuals must use the sources of radiation only under the direction of a supervisor. They must follow those procedures and practices established by the supervisor. All users are required to attend a Radiation Safety Training Seminar before they begin work (See Appendix 2: Training of Workers).

2. Radiation Regulations, Policies, Procedures and Practices

Federal Regulations

The Nuclear Regulatory Commission has established "Standards for Radiation Protection" 10CFR20. These standards must be strictly adhered to during all uses of by-product material. The NRC also has adopted regulations which assure that workers will be advised of the sources of radiation being used, the hazards, the safety precautions in effect, etc. at the place of employment. These rights are present in "Notice of Instructions and Reports to Workers: Inspections" 10CFR19.

Proteome, Inc. Policies and Procedures

The management of Proteome, Inc. recognizes both the NRC regulations and company policy of preventing unnecessary exposures to radiation as the basic criteria for establishing the radiation safety policies and procedures. The principal means by which the company assures the safe use of sources of radiation are:

1. To require that a person be authorized to use or to supervise the use of radiation sources.

2. To require that the acquisition of radiation sources be approved by the RSO and that all receipts and transfers, including disposal of radioisotopes, be channeled through the RSO.

Specific procedures and practices have been established for most routine or recurrent situations to assure compliance to the regulations and company policy. For unusual situations, the RSO will interpret the existing regulations, policies and procedures to establish guidelines.

Procedures and practices have been established and are found in the Appendices of this Guide.

1. Authorization to Use Radioisotopes
2. Training of Workers
3. Personnel Monitoring
4. ALARA Program
5. Use of Radioisotopes
6. Special Procedures

2. Radiation Regulations, Policies, Procedures and Practices

Federal Regulations

The Nuclear Regulatory Commission has established "Standards for Radiation Protection" 10CFR20. These standards must be strictly adhered to during all uses of by-product material. The NRC also has adopted regulations which assure that workers will be advised of the sources of radiation being used, the hazards, the safety precautions in effect, etc. at the place of employment. These rights are present in "Notice of Instructions and Reports to Workers: Inspections" 10CFR19.

Proteome, Inc. Policies and Procedures

The management of Proteome, Inc. recognizes both the NRC regulations and company policy of preventing unnecessary exposures to radiation as the basic criteria for establishing the radiation safety policies and procedures. The principal means by which the company assures the safe use of sources of radiation are:

1. To require that a person be authorized to use or to supervise the use of radiation sources.

2. To require that the acquisition of radiation sources be approved by the RSO and that all receipts and transfers, including disposal of radioisotopes, be channeled through the RSO.

Specific procedures and practices have been established for most routine or recurrent situations to assure compliance to the regulations and company policy. For unusual situations, the RSO will interpret the existing regulations, policies and procedures to establish guidelines.

Procedures and practices have been established and are found in the Appendices of this Guide.

1. Authorization to Use Radioisotopes
2. Training of Workers
3. Personnel Monitoring
4. ALARA Program
5. Use of Radioisotopes
6. Special Procedures

Professional Standards

The RSO also uses as operational guides the published data and recommendations of professionally recognized national and international committees and organizations concerned with health physics or radiation protection, examples of which are:

1. National Council on Radiation Protection
2. International Committee on Radiation Protection (ICRP)
3. International Atomic Energy Agency (IAEA)
4. Health Physics Society (HPS)

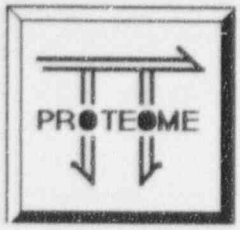
APPENDIX 1

AUTHORIZATION TO USE SOURCES OF RADIATION

An individual may use or possess radioactive materials only after (s)he has presented evidence of proper training and experience, has read the Proteome, Inc. Radiation Safety Guide, and has received training on the practical aspects of Radiation protection from the RSO or an outside consultant (See Radiation Safety Program Training Outline in Appendix 2). Retraining and continuing education occur at least annually by the RSO or an outside consultant. Technique-specific training is provided by the supervisor. An authorization form must be submitted to the RSO and the RSO must approve the application.

The authorization will be reviewed and updated when the company NRC license is submitted for renewal.

A copy of the Authorization to Use Form is on the next page.



Proteome, Inc.

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Instructions. Complete this form and submit to Radiation Safety Officer. Authorization for use requires approval of Radiation Safety Officer.

Name of Applicant **Social Security Number of Applicant**

Department & Supervisor **Location where Isotopes will be used or stored**

Radioactive material(s):

List chemical symbol and mass number of each **Form of Material (Chemical and/or Physical)**

Previous Training and Education

Subject Covered	On-Job Training Yes/No	Hours	Institution	Dated Completed

Previous Experience (actual use of radioactive materials)

Isotope	Maximum Activity per experiment	Where Used	Duration of use	Type of Use

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

I have read, do understand, and agree to abide by the Proteome, Inc. Radiation Safety Program.

Applicant's Signature: _____ Date: _____

RSO Signature (Approval): _____ Date: _____

Date of Proteome, Inc. Training Course: _____

APPENDIX 2

TRAINING OF WORKERS

Individuals using radioisotopes under an NRC license have certain rights as prescribed in 10CFR19 "Notices, Instructions and Reports to Workers: Inspections" . In accordance with part 19, a copy of the Proteome, Inc. license and a copy of the Notice to Workers (see page 14) are posted in radioisotope areas to advise persons in those areas where work is being done and to describe the documents and regulations pertinent to that work that are available from the Radiation Safety Officer.

The RSO is in charge of Radiation Safety Training at Proteome, Inc. Either the RSO or an independent consultant will conduct the training.

Proteome, Inc. has designed its training program to assure that all persons working in or frequenting areas of radioisotope usage are aware of the attendant hazards. All persons using radioisotopes or frequenting areas where radioisotopes are used must attend the Training Seminar which covers the material shown on the following pages. The RSO shall keep records of attendance at these orientations.

Training will also be provided by the RSO or the outside Radiation Safety Consultant for ancillary personnel (custodial and maintenance) who may frequent areas where radioactive material is stored or used. All ancillary workers must attend a training session before working in rooms or on equipment that may contain radioactive material.

All new staff who work in an area or at a job function where they may encounter hazardous chemicals, biohazardous materials, or radioactive materials must go through the Proteome, Inc. Laboratory Safety Orientation Program.

Annual re-training seminars will be provided for ALL radiation workers.

Radiation Safety Training Program Outline

I. Fundamentals of Radiation Safety

- A. Characteristics of Radiation
- B. Units of Radiation Dose and Quantity of Radioactivity
- C. Math and Calculations Basic to the Use and Measurement of Radioactivity
- D. Significance of Radiation Dose
  1. Radiation Protection Standards
  2. The ALARA Principle
  3. Biological Effects of Radiation
- E. Levels of Radiation from Sources of Radiation
- F. Methods of Controlling Radiation Dose
  1. Working Time
  2. Working Distance
  3. Shielding

II. Radiation Detection Instrumentation to be Used

- A. Use of Radiation Survey Instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey Techniques Including Wipe Tests
- C. Use of Personnel Monitoring Equipment
  1. Film Badges
  2. Thermoluminescent Dosimeters (TLD's)
  3. Pocket Dosimeters

III. Safety Equipment to be Used

- A. Remote Handling Equipment
- B. Fume Hoods
- C. Storage Containers
- D. Personnel Protective Equipment (i.e., gloves, lab coats, respirators.)

IV. The Requirements of Pertinent Federal and State Regulations (see Section I.D. of guide)

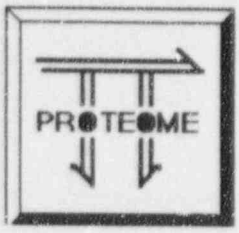
V. Terms and Conditions of the Licence, Active Amendments, and Any Correspondance Submitted in Support of the License Application

VI. The Licensee's Written Operating and Emergency Procedures

Radiation Safety Training Program Outline (con'd)

VII. Manufacturers' Instruction Manuals for Sources/Devices

VIII. On-the-Job Training.



Proteome, Inc.

CAUTION

Work with sources of radiation is being carried out in this area

In accordance with the United States Nuclear Regulatory Commission Regulation 10CFR19.11, the following documents relating to the work are available to you from the Radiation Safety Officer.

1. 10CFR20 which describes the Nuclear Regulatory Commission for Radiation protection which must be adhered to in the use of sources of radiation.

2. 10CFR19 which describes the Nuclear Regulatory Commission Regulations pertaining to notices, instructions, and reports to workers and inspections of radiation activities.

3. Regulatory License and Applications which specify the special conditions under which radiation work must be carried out.

4. Proteome, Inc. Radiation Safety Guide which specifies (Proteome, Inc.) Radiation Safety Policies and Procedures

Radiation Safety Training Program Outline (con'd)

VII. Manufacturers' Instruction Manuals for Sources/Devices

VIII. On-the-Job Training.

CAUTION

Work with sources of radiation is being carried out in this area

In accordance with the United States Nuclear Regulatory Commission Regulation 10CFR19.11, the following documents relating to the work are available to you from the Radiation Safety Officer.

1. 10CFR20 which describes the Nuclear Regulatory Commission for Radiation protection which must be adhered to in the use of sources of radiation.

2. 10CFR19 which describes the Nuclear Regulatory Commission Regulations pertaining to notices, instructions, and reports to workers and inspections of radiation activities.

3. Regulatory License and Applications which specify the special conditions under which radiation work must be carried out.

4. Proteome, Inc. Radiation Safety Guide which specifies (Proteome, Inc.) Radiation Safety Policies and Procedures

Custodial & Maintenance Instructions

What to do About Radioactive Materials

1. Rooms which have the radiation symbol shown on doors or on equipment may contain radioactive materials. You must be careful when working in these rooms. You can sweep, mop, and wax the floors and remove the waste which is not labeled with the radiation symbol, just as in any other room.

2. Any container (box, bottle, carton, etc.) which has radioactive material in it will be labeled with the Radiation Symbol. If the contents of these containers are spilled, DO NOT TOUCH THEM OR ATTEMPT TO CLEAN THEM UP. Tell your supervisor or the Radiation Safety Officer (RSO).

3. DO NOT empty any waste container which has the radiation symbol on it.

4. DO NOT empty any unlabeled waste container if it has waste material in it, such as boxes or bottles, with the radiation symbol on it. Tell your supervisor about it.

5. DO NOT eat, drink, smoke or apply cosmetics in any lab or in any room which has the radiation symbol on its door. DO NOT dispose of food, drink, cans or wrappers in laboratory trash.

6. Before you work on or around a device or on a piece of equipment with a radiation symbol on it, contact the RSO so the device may be checked for safety.

7. If you think you may have gotten some radioactive material on your skin or clothing, call the RSO immediately. (S)he will assist with proper removal and decontamination.

8. In an emergency, or if you have any questions, ask your supervisor or the RSO for help.

APPENDIX 3

PERSONNEL MONITORING

General Information

The RSO determines the need for personnel dosimetry during the authorization evaluation or evaluation of amendment requests. Authorized supervisors have the responsibility to assure that all personnel who use radioisotopes or work in their areas wear appropriate radiation dosimeters when required.

Proteome, Inc. requires all personnel using or routinely exposed to radioisotopes to wear film badges. Badges are supplied and analyzed monthly by R.S. Landauer, Jr. and Company, 39 Milltown Road, East Brunswick, NJ 08816. Personnel using 1 mCi or more of P-32 are also required to wear finger rings. Monitoring reports are returned to the RSO, who reviews them to assure that exposures are maintained within acceptable levels and in accordance with ALARA program goals (see Appendix 4).

Glossary of Selected Terms in this Appendix

Annual limit on intake (ALI) is a derived limit for the amount of radioactive material taken into the body of a worker by inhalation or ingestion in a year that results in a CEDE of 5 rem or a CDE of 50 rem.

Committed dose equivalent (CDE) is the dose equivalent to an organ or tissue that will be received from an intake of radioactive material by an individual during the 50-year period following intake.

Committed effective dose equivalent (CEDE) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to them.

Declared pregnant woman means a woman who has voluntarily informed her employer, in writing of her pregnancy and the estimated date of conception.

Deep dose equivalent (DDE), which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 centimeter.

Derived air concentration (DAC) is the concentration of a given radionuclide in air which, if breathed for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI.

Dose equivalent (DE) is the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

External dose is that portion of the dose equivalent received from radiation sources outside the body.

Eye dose equivalent refers to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter.

Internal dose is that portion of the dose equivalent received from radioactive material taken into the body.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits. It needs prior approval and must meet very specific and limiting criteria specified in 10CFR20.1206.

Shallow dose equivalent (SDE), which applied to the external exposure of the skin or an extremity, is the dose equivalent at a tissue depth of 0.007 centimeter averaged over an area of 1 square centimeter.

Total effective dose equivalent (TEDE) is the sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Maximum Permissible Dose Levels

Personnel monitoring devices are required by law, and records must be kept if an individual received, or is liable to receive, a dose in any calendar quarter in excess of 10% of the values listed in this section. "Maximum Permissible Dose Levels" (10% of these values for individuals under 18).

Such monitoring will normally take the form of film badges worn on the chest or at the waist. It is mandatory in all areas requiring a "Radiation Area" sign. Where the hand dose may exceed 10% of the relevant limit listed in this section, finger, ring, or wrist dosimeters must be worn.

Situations may occur where special precautions are dictated by unusual levels of radiation, variations of these levels, or the kind of radiation. When there are reasons to suspect that such a situation exists, it should be discussed with the RSO who will recommend proper procedures.

APPENDIX 3

PERSONNEL MONITORING

General Information

The RSO determines the need for personnel dosimetry during the authorization evaluation or evaluation of amendment requests. Authorized supervisors have the responsibility to assure that all personnel who use radioisotopes or work in their areas wear appropriate radiation dosimeters when required.

Proteome, Inc. requires all personnel using or routinely exposed to radioisotopes to wear film badges. Badges are supplied and analyzed monthly by R.S. Landauer, Jr. and Company, 39 Milltown Road, East Brunswick, NJ 08816. Personnel using 1 mCi or more of P-32 are also required to wear finger rings. Monitoring reports are returned to the RSO, who reviews them to assure that exposures are maintained within acceptable levels and in accordance with ALARA program goals (see Appendix 4).

Glossary of Selected Terms in this Appendix

Annual limit on intake (ALI) is a derived limit for the amount of radioactive material taken into the body of a worker by inhalation or ingestion in a year that results in a CEDE of 5 rem or a CDE of 50 rem.

Committed dose equivalent (CDE) is the dose equivalent to an organ or tissue that will be received from an intake of radioactive material by an individual during the 50-year period following intake.

Committed effective dose equivalent (CEDE) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to them.

Declared pregnant woman means a woman who has voluntarily informed her employer, in writing of her pregnancy and the estimated date of conception.

Deep dose equivalent (DDE), which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 centimeter.

Derived air concentration (DAC) is the concentration of a given radionuclide in air which, if breathed for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI.

Dose equivalent (DE) is the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

External dose is that portion of the dose equivalent received from radiation sources outside the body.

Eye dose equivalent refers to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter.

Internal dose is that portion of the dose equivalent received from radioactive material taken into the body.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits. It needs prior approval and must meet very specific and limiting criteria specified in 10CFR20.1206.

Shallow dose equivalent (SDE), which applied to the external exposure of the skin or an extremity, is the dose equivalent at a tissue depth of 0.007 centimeter averaged over an area of 1 square centimeter.

Total effective dose equivalent (TEDE) is the sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Maximum Permissible Dose Levels

Personnel monitoring devices are required by law, and records must be kept if an individual received, or is liable to receive, a dose in any calendar quarter in excess of 10% of the values listed in this section. "Maximum Permissible Dose Levels" (10% of these values for individuals under 18).

Such monitoring will normally take the form of film badges worn on the chest or at the waist. It is mandatory in all areas requiring a "Radiation Area" sign. Where the hand dose may exceed 10% of the relevant limit listed in this section, finger, ring, or wrist dosimeters must be worn.

Situations may occur where special precautions are dictated by unusual levels of radiation, variations of these levels, or the kind of radiation. When there are reasons to suspect that such a situation exists, it should be discussed with the RSO who will recommend proper procedures.

Maximum Permissible Dose Levels (con'd)

Occupational Dose Limits for Adults (18 or more years)

a. An annual limit (except for planned special exposures), which is the more limiting of

   i. TEDE of 5 rems (0.05Sv) or
   ii. Sum of DDE and CDE to any individual organ or tissue (except lens of eye) being equal to 5 rems (0.05Sv)

b. The annual limits to the lens of the eye, skin, extremities which are:

   i. Eye Dose Equivalent of 15 rems (0.15Sv), and
   ii. A SDE of 50 rems (0.50Sv) to the skin or to any extremity

Occupational Dose Limits for Minors (under 18 years of age)

The annual occupational dose limits for minors are 10% of the annual dose limits specified for adult workers above.

Dose to Embryo/Fetus

a. The dose to the embryo/fetus during the entire pregnancy, due to occupational exposure to a declared pregnant woman, shall not exceed 0.5 rem (5mSv).

b. In addition to the preceding paragraph, efforts shall be made to avoid substantial variation above a uniform monthly exposure of 50 mrem (0.5mSv) to a declared pregnant woman.

Dose limited for individual member of the public

a. The TEDE to individual members of the public from NRC licensed activities shall not exceed 0.1 rem (1 mSv) in a year [with exceptions specified in 10 CFR 20.301 (a) and 20.301 (c)] and

b. The dose in any unrestricted area from external sources shall not exceed 2 mrem (0.02mSv) in any one hour.

APPENDIX 4

ALARA PROGRAM

Proteome, Inc. has a policy for minimizing radiation exposures to individuals to the environment resulting from work with radioactive materials. This policy is known as ALARA, an acronym for As Low As Reasonably Achievable. The program is based on the Nuclear Regulatory Commission's definition of ALARA (which is maintaining exposures as far below the regulatory limits as practical with consideration of economics, state of technology, and other societal and socioeconomic considerations). To be effective, the program seeks to establish goals which are accepted by all levels of management and by those involved in the use of radioactive material.

Responsibilities

The RSO is responsible for maintaining oversight of activities under the ALARA Program. S/he reviews measures to achieve ALARA. S/he conducts a comprehensive annual audit of the Radiation Protection Program including the effectiveness of adherence to ALARA concepts. This audit includes review of operational procedures, authorization approvals, radiation incidents, radiation dose records, and environmental release data.

Authorized supervisors (AS) are responsible for executing the ALARA Program through the following measures:

a. Following ALARA guidelines in reviewing and approving uses of radioactive materials and recommend modifications to experiments where indicated.

b. Using measures to achieve ALARA, such as use of protective devices, operational controls and consideration of ALARA in designing experiments.

c. Formulating written procedures where applicable in specific instances.

d. Providing specific training and guidance necessary to meet the goals of the ALARA Program.

Program Goals

ALARA Goals for occupational exposures to radiation are summarized in Table 1 below.

Table 1

ALARA PROGRAM GOALS AND INVESTIGATION LEVELS

	Regulatory Limit	Goal	Investigation Levels*
Whole Body Exposures	5000 mrem/yr	500 mrem/yr	250-50% of goal
Lens of the Eye	15,000 mrem/yr	1500 mrem/yr	750-50% of goal
Skin and/or Extremity	50,000mrem/yr	5000 mrem/yr	2500-50% of goal
Minors (whole body)	100 rem/yr	50 mrem/yr	10-20% of goal
Embryo/Fetus	500 mrem in the 9 month gestation period	50 mrem in the 9 month gestation period	10-20% of goal
Member of public on site	100 mrem/yr	50 mrem/yr	10-20% of goal

*(mrem per calendar year)

ALARA Investigatory Levels Program

The ALARA (As Low As Reasonably Achievable) Program implemented by the NRC establishes "Investigatory Levels" which, when exceeded, will initiate review or investigation by the Radiation Safety Officer.

For occupational exposed individuals we have established the investigatory levels detailed in Table 1. Quarterly exposures to persons in excess of these amounts would be reviewed and investigated by the RSO and discussed by the Proteome, Inc. Safety Committee.

The Proteome, Inc. Safety Committee will specify other ALARA action levels and goals as required in 10CFR20.

APPENDIX 5

USE OF RADIOISOTOPES

The authorized supervisor is responsible for seeing that the users of radioisotopes under his or her authorization comply with all the governmental regulations, the specific conditions and limitations of his or her authorization, and the procedures and practices outlined in this Appendix. (S)he ascertains that all persons who use radioisotopes under the coverage of this authorization are supervised, properly trained and experienced, aware of the attendant hazards, and observe the procedures of this guide.

Training and Experience

See Appendix 2 of this guide.

Receipt, Transfer and Disposal of Radioactive Material

All radioisotopes must be shipped to this address:

Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

Purchase orders for all radioactive materials must be approved by the RSO.

All radioisotopes, when received, will be placed in a secured holding area. The receiving personnel will check for contamination, dose rates at the surface of the package and at one meter, and record receipt. See Appendix 6 for detailed procedures and receipt forms.

All radioactive material must be disposed of through procedures approved by the RSO. Only those amounts of liquid radioactive waste allowed by law may be disposed of down the drain of designated sinks. Liquid waste, which is not to be disposed of down the drain, must be placed in a properly labeled plastic container. Solid waste must be placed in a properly labeled container lined with a plastic bag. Liquid scintillation vials must be kept separate. See Appendix 6 for detailed procedures and inventory forms.

Radiation Surveys

Authorized users conduct routine radiation and contamination surveys of their areas. The user must conduct these routine surveys as follows:

> RADIATION SURVEYS ARE TO BE MADE BY THE USER AFTER EACH EXPERIMENTAL RUN OR AT THE END OF THE DAY IN ORDER TO DETERMINE THE EXTENT OF RADIOACTIVE CONTAMINATION AND TO ASCERTAIN THAT ALL WASTE AND STOCK MATERIAL HAVE BEEN STORED OR PROPERLY DISPOSED OF.

In addition, the RSO or a designated independent consultant will conduct monthly surveys of all lab areas. All labs are surveyed with an appropriate calibrated survey meter. Wipe tests are taken on all bench tops, hood ledges, sink areas, storage and waste disposal areas. Surveys will also check for proper labeling, signage, and adherence to rules and regulations by users.

When material is known to have been spilled or become airborne, wipe test surveys of the affected area must be made. Such tests can be made with filter paper or squares of any absorbent paper and the wipes counted with an appropriate counting instrument. The RSO must be called if a researcher has reason to believe his work has resulted in gross contamination or constitutes an emergency situation. (See Emergency Procedures below.)

For removal contamination, results from wipe tests must be less than 200 dpm/100cm^2 for C-14, H-3, P-32, P-33, and S-35. If levels are found to be higher that these limits, the area must be decontaminated and re-surveyed until all counts fall below these limits.

Results of all surveys, whether by the RSO, an independent consultant, or authorized user, including surveys using the GM probe survey instrument, will be recorded in the survey data notebook. The survey data notebook will be maintained by the RSO for inspection by the NRC.

Storage of Radioisotopes

Radioisotopes must be stored securely to permit access only to authorized users. Each area and room where radioisotopes are stored must be posted with a "Radioactive Material" sign. Radiation levels around storage areas must be measured. If radiation doses could exceed five (5) millirem per hour in an occupiable area, the area must be posted with a "Radiation Area" sign. Proper signs may be obtained from the RSO.

Storage of Radioisotopes (con'd)

Proteome, Inc. 'decay-stores' waste from P-32 ($T_{1/2}$ 14 days), P-33 ($T_{1/2}$ 25 days) and S-35 ($T_{1/2}$ 87 days). Paper, plastic, and other lab trash expendables are securely stored in covered metal containers, by isotope, in a dedicated, lockable storage room for 10 half lives. The waste is monitored with a survey meter and discarded in the trash only when no radiation above background is detectable.

Long-lived isotopes (3-H, 14-C) will be stored on-site until shipped to an offsite disposal facility is arranged through a licensed shipper.

See Appendix 6 for Radioisotope Inventory Form.

Records

A receipt log book will be kept in the radiation holding area to record the receipt of radioactive materials. Log sheets for use and disposal will be kept and posted in appropriate areas. A survey log form will also be used to record the date and results of radiation and contamination surveys, even when the results are negative. Master radioactive material inventory sheets for each isotope will be kept by the RSO based on the information derived from the user logs. See Appendix 6 for examples of these logs.

Other records required by federal law are kept by the RSO.

Records regarding receipt, inventory, survey, and disposal shall be kept for 3 years. Personal dose records shall be kept indefinitely.

Restriction of Radioisotopes Areas

Access to areas where radioisotopes are stored and used must be restricted to those persons cognizant of the associated hazards.

Radioactive Waste

Radioactive waste must be disposed of through procedures approved by the RSO. No waste is to be washed down drains or otherwise disposed of without prior clearance from the RSO. A copy of the detailed procedures for waste disposal is given in Appendix 6.

Security

All rooms containing radioactive materials or the rooms leading to them must be locked when no trained personnel are present. Furthermore, storage areas, (freezers or refrigerators) containing radioactive materials, should be kept locked except during

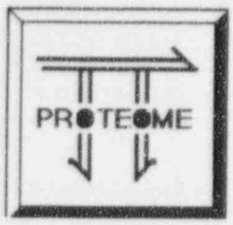
periods when trained personnel are present. Storage areas for radioactive waste must be locked at all times.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES

Eating , drinking, smoking	Eating, drinking, smoking or using cosmetics is not permitted in this laboratory.
Wash hands	Wash hands after handling any radioactive material before going about other work.
Pipetting	**Never** pipette anything, even water, by mouth.
Eye wear	Always wear safety glasses in the laboratory. See Chemical Hygiene plan outlining Proteome, Inc. policy.
Protective Clothing	Always use rubber, plastic, latex gloves when handling radioisotopes. protective gloves must be removed before leaving the laboratory to avoid contaminating doorknobs and telephones. Lab coats must be worn in the lab and left in the laboratory. Open toe sandals are not allowed in the laboratory.
Confine the Activity	Always work over trays. Keep and transport radioactive materials doubly contained.
Spills	Notify the Radiation Safety Officer of all spills.
Labeling	Label radioactive material with your name, date, isotope and quantity of isotope.
Before Leaving	Before leaving the laboratory, clean up and monitor your work area and yourself.
*Disposal of **Liquid***	Liquid radioactive materials must be stored in plastic containers or in metal containers if the material is incompatible with plastic. The quantity of isotope, the isotope name, date, and the user's name must be recorded in a log kept with the container. A log is also kept of all liquids disposed of at designated sinks.

periods when trained personnel are present. Storage areas for radioactive waste must be locked at all times.



Proteome, Inc.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES

Eating , drinking, smoking	Eating, drinking, smoking or using cosmetics is not permitted in this laboratory.
Wash hands	Wash hands after handling any radioactive material before going about other work.
Pipetting	**Never** pipette anything, even water, by mouth.
Eye wear	Always wear safety glasses in the laboratory. See Chemical Hygiene plan outlining Proteome, Inc. policy.
Protective Clothing	Always use rubber, plastic, latex gloves when handling radioisotopes. protective gloves must be removed before leaving the laboratory to avoid contaminating doorknobs and telephones. Lab coats must be worn in the lab and left in the laboratory. Open toe sandals are not allowed in the laboratory.
Confine the Activity	Always work over trays. Keep and transport radioactive materials doubly contained.
Spills	Notify the Radiation Safety Officer of all spills.
Labeling	Label radioactive material with your name, date, isotope and quantity of isotope.
Before Leaving	Before leaving the laboratory, clean up and monitor your work area and yourself.
*Disposal of **Liquid***	Liquid radioactive materials must be stored in plastic containers or in metal containers if the material is incompatible with plastic. The quantity of isotope, the isotope name, date, and the user's name must be recorded in a log kept with the container. A log is also kept of all liquids disposed of at designated sinks.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES (Con'd)

*Disposal of **Solid***	Solid radioactive waste must be placed in plastic-lined metal boxes or containers. When filled, the contents are transferred to a drum in the waste storage area.
Hoods	Materials which could become airborne must be stored and used in a hood. Hood ventilation shall be left "ON" at all times when containing such materials.
Food	Never keep or store beverages or food in radioisotope labs, in refrigerators or freezers with radioisotopes.

Emergency Procedures

A radiation emergency occurs when a set of circumstances results in hazardous radiation levels, hazardous concentrations of airborne isotopes, or gross contamination of property. Examples of radiation emergencies and actions to be taken are:

a. Personnel Contamination
   1. Remove contaminated clothing.
   2. Wash contaminated skin with mild soap and water. Do not use abrasives.
   3. Call the RSO. After hours, refer to the emergency list.

b. Spill of radioisotope where the radioisotope does not become airborne
   1. Wipe up with absorbent paper using a blotting motion so you do not spread contamination.
   2. Dispose of contaminated paper in radioactive waste container.
   3. Call the RSO. After hours, refer to the emergency list.

c. Volatilization of liquid or dispersal of solid radioisotopes outside a ventilated enclosure
   1. If possible, keep contamination localized by closing doors and restricting access to area. (Do NOT shut off hood.)
   2. Leave the area.
   3. Call the RSO. After hours, refer to the emergency list.

d. Fire in radioisotope area
   1. Treat fire in normal manner.
   2. Call the RSO. After hours, refer to the emergency list.

ALWAYS USE COMMON SENSE IN HANDLING RADIATION EMERGENCIES AND CALL THE RSO AS SOON AS PRACTICAL. DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREA.

PROTEOME, INC.

RADIATION SAFETY OFFICER	Dr. James I Garrels
DAYTIME PHONE:	(508) 922-1643
WEEKENDS AND EVENINGS:	(508) 921-0709 Refer to the emergency call list.

See following page for detailed procedures.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

Emergency Procedures

Be prepared for an emergency by mentally rehearsing the following:

EXTREME HAZARDS

Hazards such as high radiation levels or the possibility of airborne contamination from dry or volatile radioactive materials.

Evacuate	Evacuate the laboratory immediately; close the door and lock it.
Call RSO	Call the RSO immediately. If you have to leave the area to do so, remove your shoes if you suspect contamination and do not touch anything unnecessarily.

OTHER HAZARDS

Hazards such as spills or suspected spills of radioactive material where the material does not become airborne.

Keep calm	Keep calm, use common sense, protect people, do not spread contamination (Always assume you are contaminated until a survey proves otherwise.).
Confine contamination	Localize the spill. Right tipped container. Drop absorbent material on the spill. Damp down a dry spill. Do not track contamination about the laboratory. **If possible, call, do not go for help**! Close door, and where possible adjust the ventilation to prevent spread of airborne material. Check shoes before leaving the area of a cleaned up spill.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

Emergency Procedures

(con'd)

Protect Personnel	Remove contaminated clothing and wash contaminated parts of the body with detergent. Be especially thorough in flushing out wounds. Warn other workers.
Decontaminate	If thorough washing with detergent does not remove contamination from the body, consult the RSO. You will be expected to perform the major work of decontamination of the area of your spill. The RSO will survey for contamination and advise on procedures and assist as necessary All suspected contaminated persons and areas must be monitored after decontamination and before work is resumed.

IN ALL EMERGENCIES, EXCEPT MINOR SPILLS OF RADIOACTIVE MATERIALS, THE RSO MUST BE CALLED AS SOON AS POSSIBLE.

DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

Radioisotope Laboratory Design

The design and furnishings of a laboratory must be commensurate with the hazards presented by the radioisotope and its condition of use. In practical terms some baseline requirements are that:

a. Bench tops or other surfaces on which radioisotopes will be used must either be made of or be covered with a permanently impervious surface.

b. Floors must be covered with an impervious material; properly waxed, vinyl asbestos tiles are normally acceptable.

c. Walls must have a smooth, crack-free and hole-free surface.

d. Proper room ventilation and adequate radioisotope storage must be provided.

APPENDIX 6

SPECIAL PROCEDURES

Weekly Laboratory Survey Procedure

1. Laboratory contamination surveys shall be done on a weekly basis, either by the RSO or an independent consultant, or an authorized user.

2. A survey data notebook must be kept, containing layouts of the laboratories, indicating the points at which the wipes were made, and data tables containing the results of the counting of the wipes.

3. Wipes are made using filter paper. Approximately 100 square centimeters of surface should be wiped.

4. Penetrating radiation, e.g., P-32, may be monitored with the GM probe survey instrument.

5. Results of all surveys, whether by the RSO, an independent consultant, or authorized user, including surveys using the GM probe survey instrument, will be recorded in the survey data notebook. The survey data notebook will be maintained by the RSO for inspection by the NRC.

Radioactive Material Receipt and Opening Procedure

Package Receipt

1. If the shipment appears to be damaged, ask the carrier to remain and immediately proceed to the "Package Opening" procedure below.

2. A contamination survey must be made within three (3) hours after receipt of a radioactive material shipment. Deliveries are accepted only 8 am - 5 pm Monday through Friday. No weekend deliveries.

3. Radioactive material shipments must be separated from the non-radioactive shipments upon receipt. The Radiation Safety Officer and the user must be notified immediately.

Package Opening

1. Wear gloves, a lab coat, badge and safety glasses when preparing to open the package.

2. Using the G-M survey meter, measure the radiation levels at the surface of the container and if necessary at one meter from the surface. Record the results.

3. Wipe the outside shipping container surface and count the wipes to check for contamination.

4. Open the package, and take a wipe of the primary vial containing the radioisotope (or the outside of the package if it is sterile wrapped). Count these and record the results. If there are no counts above background, the container may be discarded in regular trash; otherwise the container must be discarded with solid radiation waste.

5. Record any signs of damage to the package or to the vial.

6. If there is contamination or an excessive radiation level, check the NRC regulations (10CFR20.1906) to see if the NRC or the shipper must be notified.

7. Count the wipes in a Liquid Scintillation Counter.

Delivery of Radioisotope to User

1. Do not leave the package unattended; deliver it immediately to the user so that it may be stored correctly. If the user cannot be found, contact the supervisor of the lab where the delivery was to be made for proper disposition.

SPECIAL PRECAUTIONS FOR WORKING WITH TRITIUM

Procedure involving the handling at any one time of unsealed tritium in amounts exceeding 10 mCi require bioassay. If the tritium is in the form of a nucleotide precursor, bioassay is required for 1 mCi. If the work is performed in a suitable hood bioassay will be required for amounts 10 times those stated above.

The assay is required within 48 hours of processing the above levels of tritium, and then every 2 weeks as long as the individual continues to work with these levels. The sampling frequency may be reduced to quarterly, if after 3 months, the average urinary concentration of specimens obtained during the 3 month period does not exceed 3 uCi/liter.

If urinary excretion rates are found to exceed 5 uCi/liter, an investigation shall be undertaken to determine the cause, and corrective action shall be taken. A repeat assay shall be performed within a week.

If urinary excretion rates exceed 50 uCi/liter, in addition to the above described action, the NRC shall be notified, the case shall be referred therapeutic evaluation, and repeat assays shall be performed approximately weekly until the excretion rate is reduced to 5 uCi/liter.

Handling Procedures for Millicurie Quantities of Phosphorous-32

Phosphorous 32 emits a distribution of energetic beta particles, up to a maximum energy of 1.7 Mev, which can travel as far as 7 meters in air. The absorbed dose rate close to containers of millicurie quantities of P-32 is on the order rads/min. A significant fraction of P-32 entering the body deposits in the bone structure. The annual limit of intake is 540 microcuries.

The following procedures should offer a guide to using sources of P-32 in excess of one millicurie.

1. Prepare a written set of procedures and submit them to the RSO for approval prior to the run.

2. Avoid handling the vial directly. Use remote handling tools, such as tongs or special holders when handling the source containers.

3. Use low density shielding (e.g. a minimum of **0.3** in of plexiglas) to absorb the beta particles without generating significant amounts of X-rays by an interactive process called Bremsstrahlung. Heavy materials (high atomic number) must not be used close to the source because the Bremsstrahlung process is much more efficient for these materials. However, a small amount of lead on the outside of a plastic shield will absorb the Bremsstrahlung X-rays efficiently.

4. Always wear safety glasses to protect eyes from splashes and unnecessary radiation when working with radioactive materials.

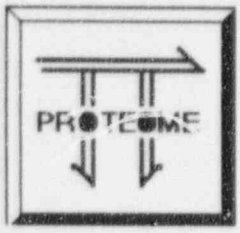
5. Wear two sets of gloves; strip the outer pair off and replace if they become contaminated. Keep the inner pair clean at all times.

6. Have immediately available a properly operating GM survey meter for use in detecting contamination and radiation fields. Surveys must be done during the procedure to evaluate the dose to the experimenter and after to check for personal contamination and bench top contamination.

7. Wear personal dosimeter and finger dosimeters. The finger dosimeters are important because they will monitor the dose given to the fingers which the body dosimeter will not see.

8. Have your supervisor or the RSO observe during your first procedure.

9. After each procedure, survey the area to check for contamination.



Proteome, Inc.

Radioisotope Receipt and Delivery

Radioisotope Ordered: _____ Activity Ordered: _____

Radioisotope Received: _____ Activity Received: _____

P.O. #: _____

Location of Use:_____

Contamination Survey

Counts per minute over 100 cm^2 area: _____ ____cpm

Efficiency of counting instrument: _____%

Contamination level (dpm) = cpm / effic. = _____dpm

Contamination level (μCi) _____dpm / 2.22 x 10^6 d/μCi = _____μCi

For All Packages:

Radiation Levels at Surface (mR/hr): _____

Radiation Levels at 1 Meter (mR/hr): _____

Acceptable levels	'1 Red Bar' package	0.5 mR/hr at surface	background at 1 meter
	'2 Red Bars' package	50 mR/hr at surface	1 mR/hr at 1 meter
	'3 Red Bars' package	200 mR/hr at surface	10 mR/hr at 1 meter

Packages above acceptable limits are held for notification to vendor, shipper, and NRC. Contact the RSO immediately.

Date and Time of Delivery to User: _____

Radioactive Waste Inventory

Disposed of empty container: _____User: _____

Date	Radioisotope	Activity	User

TOTALS: (To be completed when the radioactive waste is shipped.)

Radioisotope	Total Activity (mCi)

COLLECTION AND DISPOSAL OF RADIATION WASTE

Radioactive waste must be collected, packaged, transported, stored, and disposed or in accordance with NRC regulations. To assure compliance with these regulations, all waste must be handled according to the following instructions.

Liquid Radioactive Waste: Proteome, Inc. is allowed to dispose of liquid radioactive waste into the sanitary sewage system in accordance with 10 CFR 20.2003 provided the liquids are readily soluble in water and biologically miscible. The Proteome, Inc. procedures and limits for sink disposal of liquid radiative waste are given in Section I of Appendix VI of the Radiation Safety Guide.

Isotopes with half-lives less than 90 days: The procedures given in Section 2, Appendix VI of the Radiation Safety Guide assure that Proteome, Inc. is permitted to store waste generated by isotopes with half-lives less than 90 days on-site until decay to background (a minimum of 10 half-lives).

Waste generated in this category must be segregated at the point of collection, according to nuclide.

Isotopes with half-lives greater than 90 days: The procedures given in Section 3, Appendix VI of the Radiation Safety Guide assure that Proteome, Inc. is permitted to store 3-H and 14-C waste on-site prior to disposal by a licensed shipper.

If you have any questions, please talk to your supervisor or the RSO.

INSTRUCTIONS FOR EMPLOYEES

Waste minimization: Make sure that you adhere to the radiation waste minimizaation policy. Plan your experiments carefully and monitor the waste you generate and segregate radioactive from non-radioactive waster as it is generated.

For liquid waste, make sure the waste is readily soluble in water and that the limits for sink disposal per month have not been exceeded. Log each disposal on the log forms provided in the disposal area.

For liquid waste that is not water soluble, absorb the waste into the container provided and dispose as solid waste according to the number of the isotope.

For solid waste, clear plastic bags have been provided. When full, the bags must be fastened closed, affixed with a "caution-radioactive materials" tag, specifically noting the nuclide, the date, the activity, and the identity of the employee who completed the

tag. The bag should then be placed within one of the labeled barrels located in the laboratory. There is a designated barrel specific for each nuclide-generated waste. All radiation labels shall be removed or obliterated prior to waste being placed in plastic bags.

Please notify the RSO when barrels are full and need to be moved to the Radiation Waste Storage Room.

****Special Handling Procedures for 35-S and 33-P Waste****

- Individual plastic bags must contain no more than a maximum activity of 100uCi.
- When 3/4 full, individual plastic bags must be fastened closed such that there is enough empty space to safely "flatten" it (to increase surface area and decrease density) as it is placed into storage barrel. 35-S and 33-P are weak beta emitters. This procedure will facilitate detection of radioactivity above background at the end of 10 half-life storage.

Failure to comply with these instructions will result in the suspension of nuclide purchasing privileges.

WASTE DISPOSAL PROCEDURES

1. Disposal of Liquid Radioactive Waste into Sanitary Sewage System

Liquid radioactive waste will be disposed of in the sanitary sewage system in accordance with 10 CFR 20.2003 and the applicable concentration in Appendix B Table II. All liquids disposed in this manner will be readily soluble in water and biologically miscible as determined from Material Safety Data Sheets, the Handbook of Chemistry and Physics, and other regulatory guidelines. Any liquids that cannot meet these guidelines will be absorbed and disposed of as low level radioactive waste.

The Proteome maximum limits listed below are based on ALARA and are well within NRC maximum calculated limits which are based on a total sanitary outflow at 5 E +8 cc/month and the allowable concentrations listed in Appendix B of 10 CFR 20.

Allowable Concentrations uCi/cc (App. B)		Maximum **Calculated** Monthly Limits (in mCi)	Maximum **ALARA** Monthly Limits (in mCi)
3-H	1E-2	5000	50**
14-C	3E-4	150	7.5*
35-S	1E-3	500	50***
32-P	9E-5	45	4.5***
33-P	8E-4	400	40***

*Based on ALARA set at 5%.
**Based on ALARA set at 1%.
***Based on ALARA set at 110%.

In no case shall the annual totals of liquid effluent radioactive wastes exceed 5 Ci of 3-H, 1 Ci of 14-C, and 1 Ci of all other isotopes combined and in no case shall the monthly sum of the fractions of each nuclide disposed of in this way exceed unity. Records will be maintained to document compliance with NRC regulations and will be used to monitor monthly outflow volumes via the sanitary sewage system. The RSO

will periodically reaffirm and may, at his discretion, modify (increase or decrease) the maximum allowable monthly limits to maintain compliance with 10 CFR Part 20.2003.

Amounts disposed of must be recorded accurately and at the time of disposal, at the sink and the total per sink per month cannot exceed unity (i.e. 50% of daily limit for ^{32}P and no more than 50% of daily limit for ^{35}S).

If the aqueous waste is significantly higher than the daily limits, they can be stored in separate containers (separated by isotope).

2. Decay-in-Storage Program for solid radioactive waste with half-lives of less than 90 days.

   Solid wastes will be put into plastic bags, with a separate bag for each isotope. Bags will be labeled by nuclide, date, activity, and name of employee completing the page. These bags containing nuclides with half life less than 90 days will be placed in the radioactive waste storage room and stored for 10 half-lives. The bags will each contain a maximum of 100 uCi when placed in the decay-in-storage containers.

   When 3/4 full, each plastic bag containing 35-S or 33-P will be fastened closed such that there is enough empty space to safely "flatten" it (to increase surface area and decrease density) as it is placed into storage barrel. (Given that 35-S and 33-P are weak beta emitters, this procedure should facilitate detection of radioactivity above background at the end of 10 half life storage.) Each bag will be labeled with a "caution-radioactive materials" tag specifically noting the nuclide, the date, the activity, and the identity of the employee who completed the tag.

   When the labeled bags are moved to the Radiation Waste Storage Room, the tags will be affixed to the barrels in which the waste is placed for storage and tags will be cosigned by the RSO (or his designate) as the bags are placed into the barrels. Duplicte copies will be maintained by the RSO. Log sheets taped to each barrel will maintain a running record of the contents as bags of waste are added to each barrel, including date(s) of placement and accumulating activity.

   As each barrel becomes full, it will be sealed closed and, based upon the information on the Log Sheet for that barrel, the "OUT" date will be calculated as the earliest future date by which a minimum of 10 half-lives will have elapsed based upon the most recent (i.e. the last) bag of waste added to the barrel prior to its being closed. At the time the barrel is closed, a duplicate copy of the log sheet will be made and placed in the RSO files.

At the end of the 10 half-life storage period, the barrel will be surveyed using a pancake GM probe. The bags containing 35-S and 33-P will be flattened and given a preliminary survey. If a dose rate is detected, the barrel will be returned to storage. If there is no radioactivity above background, the barrel will be removed to an area in the facility where background radiation is low. Each plastic bag will be opened and the contents spread for survey using a pancake GM probe. With a background count of approximately 40 cpm, it is possible to detect 1.5 x background or 20 net cpm. Thus if we find a hot spot and count for a minute an efficiency of about 15%, we will be able to detect 6E-5 uCi/cpm. By counting for a full minute we are able to minimize the standard deviation at the 95% confidence level to 1.2E-4 uCi.

Records at each disposal will be kept for at least three (3) years. The records will contain the date on which the waste was put in storage, the isotopes present, the date on which it was disposed, the initials of the individual who preformed the final survey, and the results of the survey.

3. Storage and Disposal for Long Lived Radioactive Waste

Proteome, Inc. will follow the guidelines as established by the Nuclear Regulatory Commission in Information Notice 90.09.

The format below follows the outline found in NRC information Notice 90-09 and is on file with the RSO.

1. Identification of waste to be stored.

   a. It will not be necessary to increase the possession limits for extended interim storage of Low Level Waste. The possession limits have been determined to compensate for this problem with the submission of the application.

   b. Not to exceed 7.5 cubic feet per year. At most, millicurie quantities of tritium and carbon-14.

   c. All waste is CLASS A. All stored waste is solid. It is Proteome, Inc.'s policy to employ volume reduction through compaction and planned waste avoidance. The material stored will have no additional non-radiological properties.

   d. N/A

   e. The storage will not necessitate any additional permits.

2. Final Disposal Policy and Plan

a. Long-lived waste will be shipped to a low level waste site by a licensed shipper such as ADCO.

3. Physical Description of Storage Area

a. A plan identifying the location and size of the Storage Area is part of ATTACHMENT II of this application. Visual inspection and access to the drums by authorized personnel will be non-problematic. Air sampling will be conducted by portable air sampler in the room, if at all necessary. No volatiles will be in the room.

b. Maximum storage capacity is four 55 gallon steel drums, which is one drum per year for the decay-in-storage plan and one drum for long-lived waste. This will be a deposit storage based on current projections.

c. Waste storage is internal to the leased space and protected from the weather at all times.

d. The waste storage facility will be locked at all times with keys or card access controlled by the RSO.

e. General room air ventilation will be designed to operate properly and will be adequate for this type of waste.

f. The storage of the company waste will be in a room equipped and protected by the base building sprinkler system.

g. N/A

h. N/A

4. Package and Container Integrity

a. Proteome, Inc.'s policy will be to package long-lived radioactive waste in 55 gallon steel drums which are currently the accepted packaging for transportation and final disposal. The waste shall be such to pose no hazard to the integrity of the container and the container should last indefinitely.

b. Routine radiation monitoring shall be done in the storage area along with visual inspection of the stored containers.

c. N/A

5. Radiation Protection

a. The plan will call for the storage of tritium and carbon-14. There will be no radiation dose rates from the storage containers. Weekly calibrated surveys of the storage area will be done. The door to the area will be posted with the appropriate "Caution Radioactive Material" sign in accord with 10-CFR-20.1902.

b. The radionuclides and the activities to be used will not generate any dose rates and thus special shielding will not be required. Special personnel monitoring will not be necessary.

c. The name and home telephone number of the RSO will be posted on the door. The emergency procedures adopted are part of our OSHA required Chemical Hygiene Plan.

d. All drums will be appropriately labeled with the required information about the drums contents. Each bag of waste placed in storage will have a radioactive materials tag with the radionuclide, amount, date of packaging, and the person responsible for generating the waste. **[A running record will be kept on each barrel with an outdate when the ten half lives have transpired.]** A log will be maintained of the activity at any time.

6. Proteome, Inc.'s policy requires all workers handling radioisotopes including waste to attend our radiation worker training seminars which include instruction on waste minimization, packaging, handling, radiation survey techniques, and emergency procedures.

7. Financial Assurance

   a. The proposed limits in the application do not require posting of financial assurance.

8. Emergency Plan

   a. Our proposed possession limits requested at this time in this application do not require an emergency plan per 30.32 (i)(1).

JUL - 3 1996

Docket No. 030-34169
Control No. 123297

James I. Garrels, Ph.D., President
Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

Dear Dr. Garrels:

This is in reference to your application dated May 31, 1996 for a new license. In order to continue our review, we need the following additional information:

1. Your application does not name the proposed users of radioactive material and does not provide a description of training and experience specific to each user. Rather, item 7 of your application names a proposed "authorized supervisor" for your facility. Appendix 1 of your *Radiation Safety Guide* indicates that you intend to allow the Radiation Safety Officer to approve new users of licensed material.

   On a limited scope license, the qualifications of each user of licensed material are reviewed and approved by the NRC, and the users are named on the license. Provide the names of the individuals who are proposed to use licensed material under this license and provide qualifications for each user including any degrees obtained; the type (on-the-job or formal course work), location, and duration of training each individual has received in radiation safety and handling of radioactive material; and a description of the experience each individual has had handling radioactive material including the specific isotopes handled, the maximum quantities of materials handled, the company or institution at which the experience was gained, the duration, and the type of use.

2. Item 6 of your application states that you intend to perform *in vivo* studies. Submit:

   i. a description of the animal housing facilities (e.g., type of cages), and

   ii. a copy of the instructions for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

3. Appendix 6 of your *Radiation Safety Guide* states that the Radiation Safety Officer will perform documented surveys of laboratories monthly. Appendix 5 of the guide states that users must perform surveys after each experimental run or at the end of the day, but it does not appear that these surveys will necessarily be recorded. Item 6 of your application

requests authorization to use several millicuries of licensed material for labelling. Performance of weekly perform documented surveys, either by the Radiation Safety Officer or by authorized users would be appropriate for a facility using such quantities. Confirm that you will perform documented surveys at least once a week of areas in which licensed materials are used.

4. The procedures for decay-in-storage found in your *Radiation Safety Guide* do not specifically address records of disposal. Confirm that you will keep records of each disposal for at least three years and that the records will contain the date on which the waste was put in storage, the isotopes present, the date on which it was disposed, the initials of the individual who performed the final survey on the waste prior to disposal, and the results of the survey.

5. The contamination limits on page 23 of your *Radiation Safety Guide* omit phosphorus 33. Confirm that the contamination limit for this isotope will also be 200 disintegrations per minute per 100 square centimeters.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123297. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5048.

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

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

Docket No. 030-34169
Control No. 123297

Enclosures:
1. 10 CFR Parts 20 and 30
2. Regulatory Guide 3.66

DOCUMENT NAME: R:\WPS\DLTR\D3702226.02
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Brown/kdb							
DATE	07/03/96		07/ /96		07/ /96		07/ /96	

OFFICIAL RECORD COPY

PROTEOME, INC.

181 Elliott St., Suite 909, Beverly, MA 01915
TEL: (508) 922-1643 FAX: (508) 922-3971

LL 30315
030-34169
03620

May 31, 1996

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

Dear NRC Officer,

Enclosed is an Application for Material License (NRC Form 313), submitted by Proteome, Inc. for use of low level radioactive materials for biological applications. We also enclose the Proteome, Inc. Radiation Safety Guide, and a check for $1400.00 to cover the license fee.

We look forward to your approval of this application so that we can begin a new phase of our business.

Thank you.

Yours truly,

James I. Garrels, Ph.D.
President

123297

JUN - 5 1996

OFFICIAL RECORD COPY ML 10

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

U.S. NUCLEAR REGULATORY COMMISSION

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.

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

LL 30315
030-3469
03620

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*
   Proteome, Inc.
   200 Cummings Center, Suite 425C
   Beverly, MA 01915

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Proteome, Inc.
   200 Cummings Center, Suite 425C
   Beverly, MA 01915

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   James I. Garrels Ph.D.

   TELEPHONE NUMBER
   (508) 922-1643

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. See Attachment I
   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. See Attachment I

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. See Attachment III

9. FACILITIES AND EQUIPMENT. See Attachment IV

10. RADIATION SAFETY PROGRAM. See Attachment V

11. WASTE MANAGEMENT. See Attachment VI

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY 3M
    AMOUNT ENCLOSED $ $1400.

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
James I. Garrels Ph.D., President	James I. Garrels	5/31/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		123297
APPROVED BY				DATE	

NRC FORM 313 (10-94)

OFFICIAL RECORD COPY

ML 10

JUN - 5 1996

PRINTED ON RECYCLED PAPER

Attachment I

Item 5. Radioactive Material

Element and Mass No.	Chemical/Physical Form	Max Activity to be On Hand at Any One Time
Phosphorus-32	Organic and Inorganic Liquids (non-volatile)	25 mCi
Phosphorous-33	Organic and Inorganic Liquids (non-volatile)	25 mCi
Sulfur - 35	Organic and Inorganic Liquids (non-volatile)	75 mCi
Hydrogen - 3 (tritium)	Organic and Inorganic Liquids (non-volatile)	50 mCi
Carbon - 14	Organic Liquids (non-volatile)	25 mCi

Item 6. Use of Radionuclides

All radionuclides which Proteome, Inc. expects to use will be in microcurie and, occasionally, millicurie amounts. The basic nature of our research is such that radionuclides will be used in biochemical and microbiological studies for protein labeling. S-35, H-3 and C-14 will be used *in vitro* and *in vivo* protein labeling experiments. P-32 and P-33 may be used in millicuries amounts for labeling phosphorylated proteins.

The possession limits have been chosen to allow for storage of radiolabeled protein samples as reference samples for future research and to include the activity in Proteome's On Site Decay Storage Program. Review by the RSO will preclude any individual using more than required by experience and need.

Attachment II.

Item 7. Responsible Individuals (Curricula Vitae Included)

Radiation Safety Officer (RSO):	James I. Garrels Ph.D. President/Senior Scientist
Authorized Supervisors (AS)	James I. Garrels Ph.D.

Biographical Sketch and Bibliography

James I. Garrels

Educational Experience

California Institute of Technology, Pasadena, CA	B.S.	1971	Biology and Physics
University of California, San Diego, CA	Ph.D.	1978	Biology

Professional Experience

Feb. 1995 - present	President, Proteome, Inc.
1993 - Feb, 1995	Visiting Scientist, Harvard Medical School, Boston, MA,
1985 - Jan, 1995	Senior Staff Scientist and Director of the QUEST Protein Database Center, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY.
1980 - 1985	Senior Staff Investigator, Cold Spring Harbor Laboratory.
1979 - 1980	Staff Investigator, Cold Spring Harbor Laboratory.
1978 - 1979	Postdoctoral Fellow, Cold Spring Harbor Laboratory.

Awards and Memberships

Tau Beta Pi
American Society for Cell Biology
American Society for Biochemistry and Molecular Biology
Genetics Society of America
American Society for Microbiology
American Electrophoresis Society
Scientific Advisory Board, Protein Databases Inc. (1983-1988)

Outside Activities

1983-1988	Consultant, Protein Databases Inc.
1988-1994	Consultant, Millipore Corporation.

Bibliography (of 59 total)

J.I. Garrels and W. Gibson (1976) Identification and characterization of multiple forms of actin Cell, **9:** 793-805.

T. Hunter and J.I. Garrels (1977) Characterization of the mRNAs for a, b, and g actin. Cell, **12:** 767-781.

J.I. Garrels (1979) Two-dimensional gel electrophoresis and computer analysis of proteins synthesized by clonal cell lines. J. Biol. Chem., **254:** 7961-7977.

J.I. Garrels and D. Schubert (1979) Modulation of protein synthesis by nerve growth factor. J. Biol. Chem., **254:** 7978-7985.

J.I. Garrels (1979) Changes in protein synthesis during myogenesis in a clonal cell line. Devel. Biol., **73:** 134-152.

J.I. Garrels, J.T. Farrar and C.B. Burwell IV (1984) The QUEST system for computer-analyzed two-dimensional electrophoresis of proteins., In: Two-dimensional Gel Electrophoresis: Methods and Application, (ed. J.E. Celis and R. Bravo), pp. 37-91, Academic Press, New York.

M.B. Mathews, R.M. Bernstein, B.R. Franza and J.I. Garrels (1984) Identity of the proliferating cell nuclear antigen and cyclin. Nature, **309:** 374-6.

J.I. Garrels (1989) The QUEST system for quantitative analysis of two-dimensional gels. J. Biol. Chem, **264:** 5269-5282.

J.I. Garrels and B.R. Franza Jr. (1989) The REF52 protein database: Methods of database construction and analysis using the QUEST system, and characterizations of protein patterns for proliferating and quiescent REF52 cell cultures. J. Biol. Chem., **264:** 5283-5298.

J.I. Garrels and B.R. Franza Jr. (1989) Transformation-sensitive and growth-related changes of protein synthesis in REF52 cells. J. Biol. Chem, **264:** 5299-5312.

M.E. Lambert, Z.A. Ronai, I.B. Weinstein and J.I. Garrels (1989) Enhancement of major histocompatibility class I protein synthesis by DNA damage in cultured human fibroblasts and keratinocytes. Mol. Cell. Biol., **9:** 847-850.

L. Mizzen, C. Chang, J.I. Garrels and W.J. Welch (1989) Identification, characterization, and purification of two mammalian stress proteins present in mitochondria: Grp75, a member of the Hsp70 family, and Hsp58, a homolog of the bacterial groEL protein. J. Biol. Chem, **264:** 20664-20675.

J.I. Garrels, B.R. Franza, C.Chang, and G.I. Latter (1990) Quantitative exploration of the REF52 protein database: Cluster analysis reveals the major protein expression profiles in responses to growth regulation, serum stimulation, and viral transformation. Electrophoresis, **11**: 1114-1130.

K.E. Latham, J.I. Garrels, C. Chang, and D. Solter (1991) Quantitative analysis of protein synthesis in mouse embryos I: Extensive reprogramming at the one- and two-cell stages. Development, **112**: 921-932.

K.E. Latham, J.I. Garrels, C. Chang, and D. Solter (1992) Analysis of embryonic mouse development: construction of a high-resolution, two-dimensional gel protein database. Appl. Theor. Electrophoresis, **2**: 163-170.

J.I. Garrels, B.R. Franza Jr., S.D. Patterson, K.E. Latham, D. Solter, C. Chang, and G.I. Latter (1992) Protein databases constructed by quantitative 2D gel electrophoresis and protein identification from 2D gels. J. Protein Chem. **11**, 394-395.

K.E. Latham, J.I. Garrels, and D. Solter (1993) Two-dimensional gel analysis of protein synthesis. Meth Enzymol. **225**: 473-488.

P.V. Hornbeck, J.I. Garrels, Y. Capetanaki, and S. Heimer (1993) Vimentin expression is differentially regulated by IL-2 and IL-4 in murine T cells. J. Immunol. **151**:4013-4021.

K.E. Latham, R.S.P. Beddington, D. Solter, and J.I. Garrels (1993) Quantitative analysis of protein synthesis in mouse embryos. II: Differentiation of endoderm, mesoderm, and ectoderm. Mol. Reprod. and Devel. **35**: 140-150.

J.I. Garrels, B.R. Franza, Jr., S.D. Patterson, K.E. Latham, D. Solter, C. Chang, and G.I. Latter (1993) Protein databases constructed by quantitative two-dimensional gel electrophoresis. In: Methods in Protein Sequence Analysis (K. Imahori and F. Sakiyama, Eds), p. 247-253.

P.J. Monardo, T.J. Boutell, J.I. Garrels, and G.I. Latter (1994) A distributed system for two-dimensional gel analysis. CABIOS, **10** 137-143.

S.D. Patterson and J.I. Garrels (1994) Two-dimensional gel analysis of posttranslational modifications. In: Cell Biology: A Laboratory Handbook, Vol. 3 (J. E. Celis, ed.), p. 249-257, Academic Press, NY.

K.E. Latham, J.I. Garrels, and D. Solter (1994) Alterations in protein synthesis following transplantation of mouse 8-cell stage nuclei into enucleated 1-cell embryos. Dev. Biol. 163:341-350 .

J.I. Garrels, B. Futcher, R. Kobayashi, G.I. Latter, B. Schwender, T. Volpe, J.R. Warner, and C.S. McLaughlin (1994) Protein identifications for a *Saccharomyces cerevisiae* protein database. Electrophoresis **15**:1466-1486.

G.I. Latter, T. Boutell, P.J. Monardo, R. Kobayashi, B. Futcher, C. McLaughlin, and J.I. Garrels (1995) A *Saccharomyces cerevisiae* Internet Protein Resource. Electrophoresis **16**:1170-1174.

J.I. Garrels (1995) YPD — A Database for the Proteins of *Saccharomyces cerevisiae* Nucleic Acids Res. **24**:46-49.

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Instructions. Complete this form and submit to Radiation Safety Officer. Authorization for use requires approval of Radiation Safety Officer.

Name of Applicant

James I Garrels Ph.D.

Social Security Number of Applicant

Department & Supervisor

Location where Isotopes will be used or stored

company wide

Radioactive material(s):

List chemical symbol and mass number of each	**Form of Material (Chemical and/or Physical)**
all isotopes	See Attachment I of application

Previous Training and Education

Subject Covered	On-Job Training Yes/No	Hours	Institution	Date Completed
Principles and Practices of Radiation Protection	Yes	2 hr. course	Salk Institute	1972
Measurement and Monitoring Techniques	Yes	2 hr. course	Calif. Institute of Technology	1970
Mathematical Principles for Calculating Activity	Yes	3 hr. course	Cold Spring Harbor Lab	1978
Biological Effects of Radiation	Yes	2 hr. course	Harvard	1992

Previous Experience (actual use of radioactive materials)

Isotope	Maximum Activity per experiment	Where Used	Duration of use	Type of Use
^{32}P	10 mci	Salk Inst., Cal Tech, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling
^{33}P	5 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	18 yrs.	Protein Labeling
^{35}S	10 mci	Salk Inst, Cal Tech, Cold Spring Harbor, Harvard	20 yrs.	Protein Labeling
^{3}H	10 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling
^{14}C	5 mci	Salk Inst, Cold Spring Harbor Lab, Harvard	20 yrs.	Protein Labeling

Attachment III.

Item 8. Training of Individuals Working in or Frequenting Radioactive Area

The Proteome, Inc. Radiation Safety Training Program is detailed in Appendix II of the Radiation Safety Manual. Training will be provided by our outside Radiation Safety Consultant, Mr. Robert U. Johnson, former Harvard University Associate Radiation Safety Officer. Training will include sessions for ancillary workers who work in rooms or on equipment that may contain radioactive material.

Attachment IV.

Item 9. Facilities and Equipment

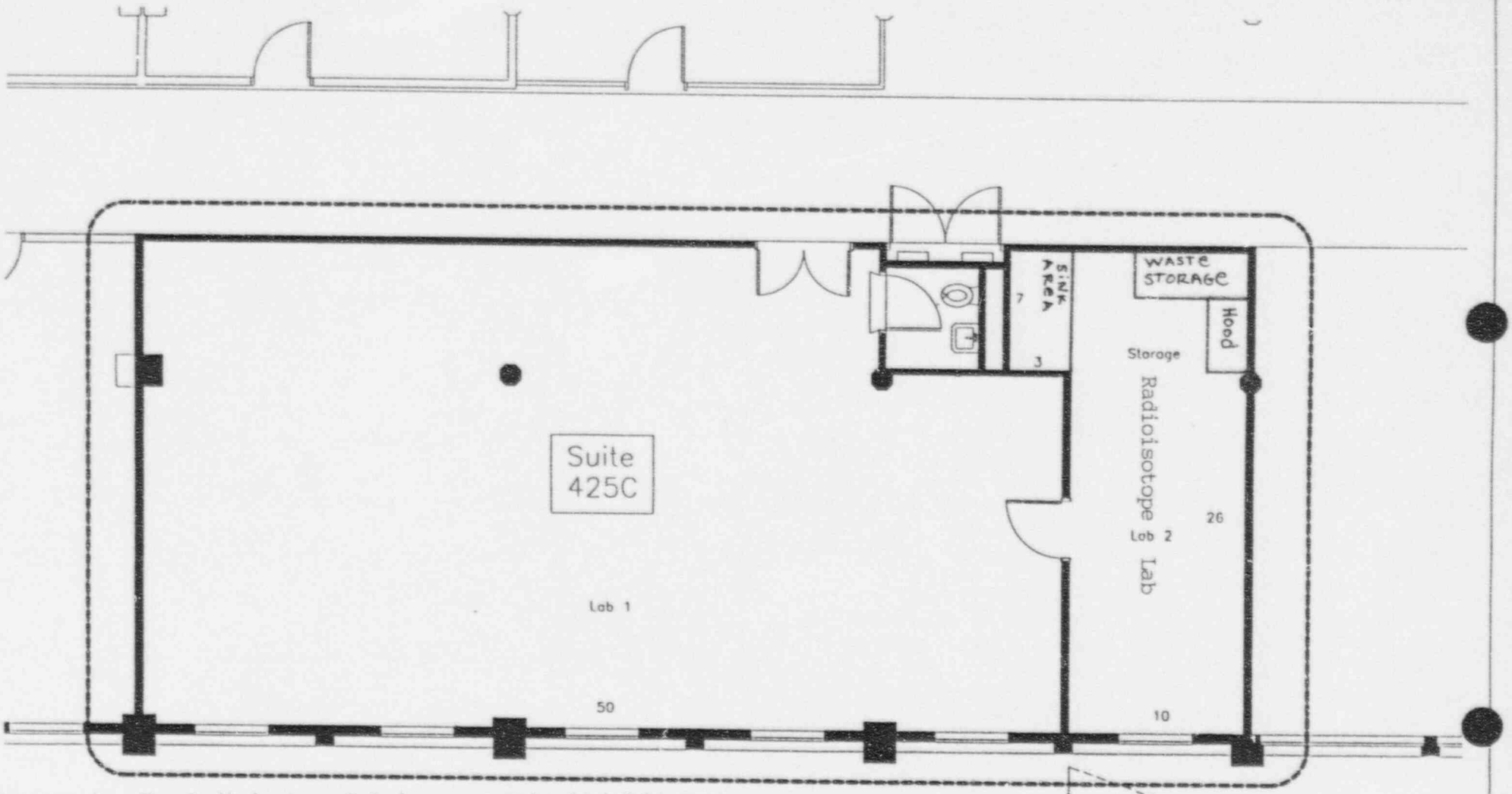
Floor plans of the Proteome, Inc. facilities in Beverly, MA are attached. The laboratory areas in which radioisotopes will be used are indicated, as is the location of the receiving area and waste storage facility.

Features:

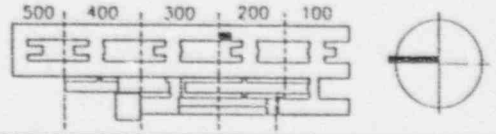
Floor covering:	Rolled seamless vinyl and vinyl tile or equivalent.
Working surfaces:	Stainless steel, Formica, epoxy coated stone or equivalent; absorbent, plastic-backed paper will be used at all times.
Hoods:	Impervious surfaces (epoxy, stainless steel, or equivalent); with minimum of 100 linear feet per minute air flow across the front of the hood opening with the hood sashes at normal height (see floor plan). The hood flow will be checked semiannually

Other:

Receiving	All shipments will be brought to the Receiving Area for check-in, radiation survey and logging.
Security	The laboratory facilities at Proteome, Inc. are locked whenever not occupied by trained personnel, and are always locked after hours and on weekends. The lab areas are segregated from the office areas and only authorized personnel are allowed into the laboratory where radioactivity is used. The rooms containing radioactive material are always locked when not in use. Waste storage areas are locked at all times.
Waste Storage:	Waste storage for both the Decay-in-Storage Plan and the storage of long-lived waste prior to shipping will be in a locked room within the inner laboratory where radioactivity is used. See the attached floor plan.



Notes:
1. The Radioisotope Lab is a separate lockable room.
2. The hood in the Radioisotope Lab measures approximately 4 feet wide by 3 feet deep.
3. A sink for disposal of radioactive waste is in the Radioisotope Lab.
4. The waste storage area is a locked area within the Radioisotope Lab.
5. The holding area for new shipment of radioactive material is in the hood.



Cummings Properties
100 Cummings Center, Beverly, MA (508) 922-9000
Corporate Offices, 200 West Cummings Park, Woburn, MA 01801 (617) 933-8000

Lease Proposal Plan

Proteome, Inc.
200 Cummings Center, Suite 425C

L.S.F.: 1959
Date : 17 APR 96
Drawn: ARC
Scale: 1"=8'-0"
Revised:

- All dimensions are approximate.
- CPMI standard construction unless otherwise noted.
- Furnishings are shown for illustrative purposes only.
- No representation is made as to the suitability of this design for Lessee's use or occupancy.

Attachment IV. (con'd)

Item 9. Radiation Detection Equipment and Calibration

Radiation Detection Equipment

1. Geiger-Mueller Survey Instruments (Quantity = 1). Additional units will be added as required.

Model:	Ludlum Model 3 with 44-9 Pancake Detector (Q=3)
Use:	Frisker for alpha, beta, gamma
Range:	0.025 to 200 mr/hr.
Check	Check source (1 μCi Cs-137)

Calibration Procedure

Instrument calibration is performed at least annually and following repair by Mr. Robert U. Johnson, Independent Consultant (and former Harvard University Associate Radiation Safety Officer) or at an NRC licensed calibration facility.

1. A calibration label is affixed to the instrument, specifying the ranges that have been calibrated and the date of calibration.

2. A certificate of calibration is provided for each instrument calibrated. Calibration certificates are kept at the company for a minimum of three years.

Attachment V.

Items 10. Radiation Protection Program

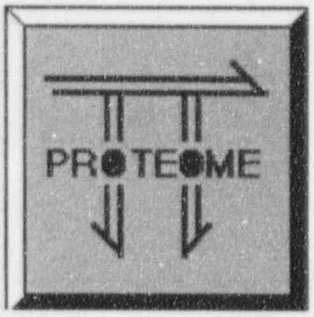
The attached Radiation Safety Guide covers all aspects of Proteome, Inc.'s Radiation Protection Program in detail. Please refer to the table of contents for specific items.

Attachment VI.

Item 11. Waste Management

The attached Radiation Safety Guide covers all aspects of Proteome, Inc.'s Waste Management Program. Please refer to Table of Contents for specific items.

Laboratory waste is collected and stored temporarily in metal containers within the laboratories. Periodically, waste is gathered, labeled by isotope, and moved to a secure Waste Storage Room for decay-in-storage and for holding of long-lived waste prior to shipping as described in the company fulfillment of Regulatory Guide 90.09. This room (see floor plan in Attachment IV) has a locked door and restricted access. It is surveyed weekly and the results logged.



RADIATION SAFETY GUIDE

1996

TABLE OF CONTENTS

INTRODUCTION

All uses of radioactive material at Proteome, Inc. are controlled by the Radiation Protection Program.

> NO WORK WITH SOURCES OF IONIZING RADIATION MAY BE INITIATED UNTIL AUTHORIZATION HAS BEEN OBTAINED FROM THE RADIATION SAFETY OFFICER.

All used of ionizing radiation (except ultra-violet radiation) in Massachusetts are controlled and regulated by the U.S. Nuclear Regulatory Commission (NRC). Proteome, Inc. has established a Radiation Safety Program to give the necessary assurances to the NRC as well as to the company management that all potentially hazardous sources of radiation will be used safely. This guide describes the organization of the program and specifies the regulations, policies and procedures and practices which are to be followed when using radioactive materials.

It is Proteome, Inc. policy that use of radioactive materials be kept to a minimum and that there be no unwarranted radiation exposure. Due regard must always be given to the safety and welfare of the radiation workers and the general population, as well as to the protection of Proteome, Inc. property and liability. Proteome, Inc.'s operational policy places responsibility on the user and persons who supervise the use of radioactive materials. Supervisors will satisfy their responsibilities by adhering to this Radiation Safety Guide and by requesting assistance from the Radiation Safety Officer (RSO) when there are questions or suspected problems.

This guide is organized in the following manner:

Section 1	General description of the Proteome, Inc. Radiation Safety Program Organization and Responsibilities
Section 2	Summary of Policies and Procedures
Appendices	Detailed Procedures and Practices

1. Description of the Proteome, Inc. Radiation Safety Program

There are three levels of authority in the Radiation Safety program:

The Radiation Safety Officer (RSO)

The RSO together with the management of Proteome, Inc. establishes the Radiation Safety Policy such that:

1. Unwarranted radiation safety exposures of Proteome, Inc. employees and general public are avoided.
2. Compliance with all the federal and state regulations is assured.
3. Proteome, Inc.'s property and liability are protected.

Duties of the Radiation Safety Officer include:

a. Ensuring that each use of radioactive material is by or under the supervision of a properly authorized supervisor.

b. Enforcing the wearing of proper dosimetry, conducting surveys of all use and storage of radioactive materials and being sure that all areas, containers, and equipment are properly labelled. This would include control of exposures of pregnant females.

c. Assuring that radioactive material is properly secured against unauthorized removal when not in use.

d. Maintaining current working records of the receipt and disposition of radionuclides including use in research, waste disposal, transfer, storage, etc.

e. Evaluating the radiological hazards by routine inspections and ensuring the implementation of appropriate radiation safety precautions.

f. Avoiding any unnecessary exposures to him/herself and others under his/her supervision in accord with ALARA.

g. Keeping an inventory of radioactive materials on hand.

h. Responsibility of compliance with all regulations governing the use of radioactive materials.

i. Limiting the use of the radionuclides to quantities and for the purposes specified in the license.

j. Ensuring the training and indoctrination of all persons using radioactive materials and ensuring that workers are properly supervised.

The Authorized Supervisor (AS)

Senior Scientists or Department Managers have primary responsibility for the radiation safety associated with each source under their control. Each AS must ascertain that persons under their supervision using these sources are properly trained and aware of the attendant hazards. Each AS must also assure that use of the sources conform to all the safety conditions of this authorization and those of this Guide.

The Supervised User (SU)

These individuals must use the sources of radiation only under the direction of a supervisor. They must follow those procedures and practices established by the supervisor. All users are required to attend a Radiation Safety Training Seminar before they begin work (See Appendix 2: Training of Workers).

2. Radiation Regulations, Policies, Procedures and Practices

Federal Regulations

The Nuclear Regulatory Commission has established "Standards for Radiation Protection" 10CFR20. These standards must be strictly adhered to during all uses of by-product material. The NRC also has adopted regulations which assure that workers will be advised of the sources of radiation being used, the hazards, the safety precautions in effect, etc. at the place of employment. These rights are present in "Notice of Instructions and Reports to Workers: Inspections" 10CFR19.

Proteome, Inc. Policies and Procedures

The management of Proteome, Inc. recognizes both the NRC regulations and company policy of preventing unnecessary exposures to radiation as the basic criteria for establishing the radiation safety policies and procedures. The principal means by which the company assures the safe use of sources of radiation are:

1. To require that a person be authorized to use or to supervise the use of radiation sources.

2. To require that the acquisition of radiation sources be approved by the RSO and that all receipts and transfers, including disposal of radioisotopes, be channeled through the RSO.

Specific procedures and practices have been established for most routine or recurrent situations to assure compliance to the regulations and company policy. For unusual situations, the RSO will interpret the existing regulations, policies and procedures to establish guidelines.

Procedures and practices have been established and are found in the Appendices of this Guide.

1. Authorization to Use Radioisotopes
2. Training of Workers
3. Personnel Monitoring
4. ALARA Program
5. Use of Radioisotopes
6. Special Procedures

Professional Standards

The RSO also uses as operational guides the published data and recommendations of professionally recognized national and international committees and organizations concerned with health physics or radiation protection, examples of which are:

1. National Council on Radiation Protection
2. International Committee on Radiation Protection (ICRP)
3. International Atomic Energy Agency (IAEA)
4. Health Physics Society (HPS)

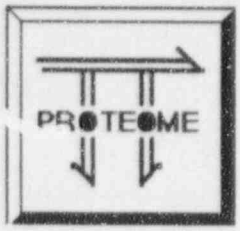
APPENDIX 1

AUTHORIZATION TO USE SOURCES OF RADIATION

An individual may use or possess radioactive materials only after (s)he has presented evidence of proper training and experience, has read the Proteome, Inc. Radiation Safety Guide, and has received training on the practical aspects of Radiation protection from the RSO or an outside consultant (See Radiation Safety Program Training Outline in Appendix 2). Retraining and continuing education occur at least annually by the RSO or an outside consultant. Technique-specific training is provided by the supervisor. An authorization form must be submitted to the RSO and the RSO must approve the application.

The authorization will be reviewed and updated when the company NRC license is submitted for renewal.

A copy of the Authorization to Use Form is on the next page.



Proteome, Inc.

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Instructions. Complete this form and submit to Radiation Safety Officer. Authorization for use requires approval of Radiation Safety Officer.

Name of Applicant **Social Security Number of Applicant**

Department & Supervisor **Location where Isotopes will be used or stored**

Radioactive material(s):

List chemical symbol and mass number of each **Form of Material (Chemical and/or Physical)**

Previous Training and Education

Subject Covered	On-Job Training Yes/No	Hours	Institution	Dated Completed

Previous Experience (actual use of radioactive materials)

Isotope	Maximum Activity per experiment	Where Used	Duration of use	Type of Use

AUTHORIZATION TO USE RADIOACTIVE MATERIALS

I have read, do understand, and agree to abide by the Proteome, Inc. Radiation Safety Program.

Applicant's Signature: _____ Date: _____

RSO Signature (Approval): _____ Date: _____

Date of Proteome, Inc. Training Course: _____

APPENDIX 2

TRAINING OF WORKERS

Individuals using radioisotopes under an NRC license have certain rights as prescribed in 10CFR19 "Notices, Instructions and Reports to Workers: Inspections" . In accordance with part 19, a copy of the Proteome, Inc. license and a copy of the Notice to Workers (see page 14) are posted in radioisotope areas to advise persons in those areas where work is being done and to describe the documents and regulations pertinent to that work that are available from the Radiation Safety Officer.

The RSO is in charge of Radiation Safety Training at Proteome, Inc. Either the RSO or an independent consultant will conduct the training.

Proteome, Inc. has designed its training program to assure that all persons working in or frequenting areas of radioisotope usage are aware of the attendant hazards. All persons using radioisotopes or frequenting areas where radioisotopes are used must attend the Training Seminar which covers the material shown on the following pages. The RSO shall keep records of attendance at these orientations.

Training will also be provided by the RSO or the outside Radiation Safety Consultant for ancillary personnel (custodial and maintenance) who may frequent areas where radioactive material is stored or used. All ancillary workers must attend a training session before working in rooms or on equipment that may contain radioactive material.

All new staff who work in an area or at a job function where they may encounter hazardous chemicals, biohazardous materials, or radioactive materials must go through the Proteome, Inc. Laboratory Safety Orientation Program.

Annual re-training seminars will be provided for ALL radiation workers.

Radiation Safety Training Program Outline

I. Fundamentals of Radiation Safety

- A. Characteristics of Radiation
- B. Units of Radiation Dose and Quantity of Radioactivity
- C. Math and Calculations Basic to the Use and Measurement of Radioactivity
- D. Significance of Radiation Dose
  1. Radiation Protection Standards
  2. The ALARA Principle
  3. Biological Effects of Radiation
- E. Levels of Radiation from Sources of Radiation
- F. Methods of Controlling Radiation Dose
  1. Working Time
  2. Working Distance
  3. Shielding

II. Radiation Detection Instrumentation to be Used

- A. Use of Radiation Survey Instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey Techniques Including Wipe Tests
- C. Use of Personnel Monitoring Equipment
  1. Film Badges
  2. Thermoluminescent Dosimeters (TLD's)
  3. Pocket Dosimeters

III. Safety Equipment to be Used

- A. Remote Handling Equipment
- B. Fume Hoods
- C. Storage Containers
- D. Personnel Protective Equipment (i.e., gloves, lab coats, respirators.)

IV. The Requirements of Pertinent Federal and State Regulations (see Section I.D. of guide)

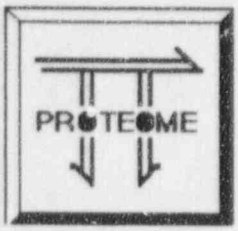
V. Terms and Conditions of the Licence, Active Amendments, and Any Correspondance Submitted in Support of the License Application

VI. The Licensee's Written Operating and Emergency Procedures

Radiation Safety Training Program Outline (con'd)

VII. Manufacturers' Instruction Manuals for Sources/Devices

VIII. On-the-Job Training.



Proteome, Inc.

CAUTION

Work with sources of radiation is being carried out in this area

In accordance with the United States Nuclear Regulatory Commission Regulation 10CFR19.11, the following documents relating to the work are available to you from the Radiation Safety Officer.

1. 10CFR20 — which describes the Nuclear Regulatory Commission for Radiation protection which must be adhered to in the use of sources of radiation.

2. 10CFR19 — which describes the Nuclear Regulatory Commission Regulations pertaining to notices, instructions, and reports to workers and inspections of radiation activities.

3. Regulatory License and Applications — which specify the special conditions under which radiation work must be carried out.

4. Proteome, Inc. Radiation Safety Guide — which specifies (Proteome, Inc.) Radiation Safety Policies and Procedures

Custodial & Maintenance Instructions

What to do About Radioactive Materials

1. Rooms which have the radiation symbol shown on doors or on equipment may contain radioactive materials. You must be careful when working in these rooms. You can sweep, mop, and wax the floors and remove the waste which is not labeled with the radiation symbol, just as in any other room.

2. Any container (box, bottle, carton, etc.) which has radioactive material in it will be labeled with the Radiation Symbol. If the contents of these containers are spilled, DO NOT TOUCH THEM OR ATTEMPT TO CLEAN THEM UP. Tell your supervisor or the Radiation Safety Officer (RSO).

3. DO NOT empty any waste container which has the radiation symbol on it.

4. DO NOT empty any unlabeled waste container if it has waste material in it, such as boxes or bottles, with the radiation symbol on it. Tell your supervisor about it

5. DO NOT eat, drink, smoke or apply cosmetics in any lab or in any room which has the radiation symbol on its door. DO NOT dispose of food, drink, cans or wrappers in laboratory trash.

6. Before you work on or around a device or on a piece of equipment with a radiation symbol on it, contact the RSO so the device may be checked for safety.

7. If you think you may have gotten some radioactive material on your skin or clothing, call the RSO immediately. (S)he will assist with proper removal and decontamination.

8. In an emergency, or if you have any questions, ask your supervisor or the RSO for help.

APPENDIX 3

PERSONNEL MONITORING

General Information

The RSO determines the need for personnel dosimetry during the authorization evaluation or evaluation of amendment requests. Authorized supervisors have the responsibility to assure that all personnel who use radioisotopes or work in their areas wear appropriate radiation dosimeters when required.

Proteome, Inc. requires all personnel using or routinely exposed to radioisotopes to wear film badges. Badges are supplied and analyzed monthly by R.S. Landauer, Jr. and Company, 39 Milltown Road, East Brunswick, NJ 08816. Personnel using 1 mCi or more of P-32 are also required to wear finger rings. Monitoring reports are returned to the RSO, who reviews them to assure that exposures are maintained within acceptable levels and in accordance with ALARA program goals (see Appendix 4).

Glossary of Selected Terms in this Appendix

Annual limit on intake (ALI) is a derived limit for the amount of radioactive material taken into the body of a worker by inhalation or ingestion in a year that results in a CEDE of 5 rem or a CDE of 50 rem.

Committed dose equivalent (CDE) is the dose equivalent to an organ or tissue that will be received from an intake of radioactive material by an individual during the 50-year period following intake.

Committed effective dose equivalent (CEDE) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to them.

Declared pregnant woman means a woman who has voluntarily informed her employer, in writing of her pregnancy and the estimated date of conception.

Deep dose equivalent (DDE), which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 centimeter.

Derived air concentration (DAC) is the concentration of a given radionuclide in air which, if breathed for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI.

Dose equivalent (DE) is the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

External dose is that portion of the dose equivalent received from radiation sources outside the body.

Eye dose equivalent refers to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter.

Internal dose is that portion of the dose equivalent received from radioactive material taken into the body.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits. It needs prior approval and must meet very specific and limiting criteria specified in 10CFR20.1206.

Shallow dose equivalent (SDE), which applied to the external exposure of the skin or an extremity, is the dose equivalent at a tissue depth of 0.007 centimeter averaged over an area of 1 square centimeter.

Total effective dose equivalent (TEDE) is the sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Maximum Permissible Dose Levels

Personnel monitoring devices are required by law, and records must be kept if an individual received, or is liable to receive, a dose in any calendar quarter in excess of 10% of the values listed in this section. "Maximum Permissible Dose Levels" (10% of these values for individuals under 18).

Such monitoring will normally take the form of film badges worn on the chest or at the waist. It is mandatory in all areas requiring a "Radiation Area" sign. Where the hand dose may exceed 10% of the relevant limit listed in this section, finger, ring, or wrist dosimeters must be worn.

Situations may occur where special precautions are dictated by unusual levels of radiation, variations of these levels, or the kind of radiation. When there are reasons to suspect that such a situation exists, it should be discussed with the RSO who will recommend proper procedures.

Maximum Permissible Dose Levels (con'd)

Occupational Dose Limits for Adults (18 or more years)

a. An annual limit (except for planned special exposures), which is the more limiting of

   i. TEDE of 5 rems (0.05Sv) or
   ii. Sum of DDE and CDE to any individual organ or tissue (except lens of eye) being equal to 5 rems (0.05Sv)

b. The annual limits to the lens of the eye, skin, extremities which are:

   i. Eye Dose Equivalent of 15 rems (0.15Sv), and
   ii. A SDE of 50 rems (0.50Sv) to the skin or to any extremity

Occupational Dose Limits for Minors (under 18 years of age)

The annual occupational dose limits for minors are 10% of the annual dose limits specified for adult workers above.

Dose to Embryo/Fetus

a. The dose to the embryo/fetus during the entire pregnancy, due to occupational exposure to a declared pregnant woman, shall not exceed 0.5 rem (5mSv).

b. In addition to the preceding paragraph, efforts shall be made to avoid substantial variation above a uniform monthly exposure of 50 mrem (0.5mSv) to a declared pregnant woman.

Dose limited for individual member of the public

a. The TEDE to individual members of the public from NRC licensed activities shall not exceed 0.1 rem (1 mSv) in a year [with exceptions specified in 10 CFR 20.301 (a) and 20.301 (c)] and

b. The dose in any unrestricted area from external sources shall not exceed 2 mrem (0.02mSv) in any one hour.

APPENDIX 4

ALARA PROGRAM

Proteome, Inc. has a policy for minimizing radiation exposures to individuals to the environment resulting from work with radioactive materials. This policy is known as ALARA, an acronym for As Low As Reasonably Achievable. The program is based on the Nuclear Regulatory Commission's definition of ALARA (which is maintaining exposures as far below the regulatory limits as practical with consideration of economics, state of technology, and other societal and socioeconomic considerations). To be effective, the program seeks to establish goals which are accepted by all levels of management and by those involved in the use of radioactive material.

Responsibilities

The RSO is responsible for maintaining oversight of activities under the ALARA Program. S/he reviews measures to achieve ALARA. S/he conducts a comprehensive annual audit of the Radiation Protection Program including the effectiveness of adherence to ALARA concepts. This audit includes review of operational procedures, authorization approvals, radiation incidents, radiation dose records, and environmental release data.

Authorized supervisors (AS) are responsible for executing the ALARA Program through the following measures:

a. Following ALARA guidelines in reviewing and approving uses of radioactive materials and recommend modifications to experiments where indicated.

b. Using measures to achieve ALARA, such as use of protective devices, operational controls and consideration of ALARA in designing experiments.

c. Formulating written procedures where applicable in specific instances.

d. Providing specific training and guidance necessary to meet the goals of the ALARA Program.

Program Goals

ALARA Goals for occupational exposures to radiation are summarized in Table 1 below.

Table 1

ALARA PROGRAM GOALS AND INVESTIGATION LEVELS

	Regulatory Limit	Goal	Investigation Levels*
Whole Body Exposures	5000 mrem/yr	500 mrem/yr	250-50% of goal
Lens of the Eye	15,000 mrem/yr	1500 mrem/yr	750-50% of goal
Skin and/or Extremity	50,000mrem/yr	5000 mrem/yr	2500-50% of goal
Minors (whole body)	100 rem/yr	50 mrem/yr	10-20% of goal
Embryo/Fetus	500 mrem in the 9 month gestation period	50 mrem in the 9 month gestation period	10-20% of goal
Member of public on site	100 mrem/yr	50 mrem/yr	10-20% of goal

*(mrem per calendar year)

ALARA Investigatory Levels Program

The ALARA (As Low As Reasonably Achievable) Program implemented by the NRC establishes "Investigatory Levels" which, when exceeded, will initiate review or investigation by the Radiation Safety Officer.

For occupational exposed individuals we have established the investigatory levels detailed in Table 1. Quarterly exposures to persons in excess of these amounts would be reviewed and investigated by the RSO and discussed by the Proteome, Inc. Safety Committee.

The Proteome, Inc. Safety Committee will specify other ALARA action levels and goals as required in 10CFR20.

APPENDIX 5

USE OF RADIOISOTOPES

The authorized supervisor is responsible for seeing that the users of radioisotopes under his or her authorization comply with all the governmental regulations, the specific conditions and limitations of his or her authorization, and the procedures and practices outlined in this Appendix. (S)he ascertains that all persons who use radioisotopes under the coverage of this authorization are supervised, properly trained and experienced, aware of the attendant hazards, and observe the procedures of this guide.

Training and Experience

See Appendix 2 of this guide.

Receipt, Transfer and Disposal of Radioactive Material

All radioisotopes must be shipped to this address:

Proteome, Inc.
200 Cummings Center, Suite 425C
Beverly, MA 01915

Purchase orders for all radioactive materials must be approved by the RSO.

All radioisotopes, when received, will be placed in a secured holding area. The receiving personnel will check for contamination, dose rates at the surface of the package and at one meter, and record receipt. See Appendix 6 for detailed procedures and receipt forms.

All radioactive material must be disposed of through procedures approved by the RSO. Only those amounts of liquid radioactive waste allowed by law may be disposed of down the drain of designated sinks. Liquid waste, which is not to be disposed of down the drain, must be placed in a properly labeled plastic container. Solid waste must be placed in a properly labeled container lined with a plastic bag. Liquid scintillation vials must be kept separate. See Appendix 6 for detailed procedures and inventory forms.

Radiation Surveys

Authorized users conduct routine radiation and contamination surveys of their areas. The user must conduct these routine surveys as follows:

> RADIATION SURVEYS ARE TO BE MADE BY THE USER AFTER EACH EXPERIMENTAL RUN OR AT THE END OF THE DAY IN ORDER TO DETERMINE THE EXTENT OF RADIOACTIVE CONTAMINATION AND TO ASCERTAIN THAT ALL WASTE AND STOCK MATERIAL HAVE BEEN STORED OR PROPERLY DISPOSED OF.

In addition, the RSO or a designated independent consultant will conduct monthly surveys of all lab areas. All labs are surveyed with an appropriate calibrated survey meter. Wipe tests are taken on all bench tops, hood ledges, sink areas, storage and waste disposal areas. Surveys will also check for proper labeling, signage, and adherence to rules and regulations by users.

When material is known to have been spilled or become airborne, wipe test surveys of the affected area must be made. Such tests can be made with filter paper or squares of any absorbent paper and the wipes counted with an appropriate counting instrument. The RSO must be called if a researcher has reason to believe his work has resulted in gross contamination or constitutes an emergency situation. (See Emergency Procedures below.)

For removal contamination, results from wipe tests must be less than 200 dpm/100cm^2 for C-14, H-3, P-32, and S-35. If levels are found to be higher that these limits, the area must be decontaminated and re-surveyed until all counts fall below these limits.

All radiation survey reports will be maintained by the RSO for inspection by the NRC.

Storage of Radioisotopes

Radioisotopes must be stored securely to permit access only to authorized users. Each area and room where radioisotopes are stored must be posted with a "Radioactive Material" sign. Radiation levels around storage areas must be measured. If radiation doses could exceed five (5) millirem per hour in an occupiable area, the area must be posted with a "Radiation Area" sign. Proper signs may be obtained from the RSO.

Storage of Radioisotopes (con'd)

Proteome, Inc. 'decay-stores' waste from P-32 ($T_{1/2}$ 14 days), P-33 ($T_{1/2}$ 25 days) and S-35 ($T_{1/2}$ 87 days). Paper, plastic, and other lab trash expendables are securely stored in covered metal containers, by isotope, in a dedicated, lockable storage room for 10 half lives. The waste is monitored with a survey meter and discarded in the trash only when no radiation above background is detectable.

Long-lived isotopes (3-H, 14-C) will be stored on-site until shipped to an offsite disposal facility is arranged through a licensed shipper.

See Appendix 6 for Radioisotope Inventory Form.

Records

A receipt log book will be kept in the radiation holding area to record the receipt of radioactive materials. Log sheets for use and disposal will be kept and posted in appropriate areas. A survey log form will also be used to record the date and results of radiation and contamination surveys, even when the results are negative. Master radioactive material inventory sheets for each isotope will be kept by the RSO based on the information derived from the user logs. See Appendix 6 for examples of these logs.

Other records required by federal law are kept by the RSO.

Records regarding receipt, inventory, survey, and disposal shall be kept for 3 years. Personal dose records shall be kept indefinitely.

Restriction of Radioisotopes Areas

Access to areas where radioisotopes are stored and used must be restricted to those persons cognizant of the associated hazards.

Radioactive Waste

Radioactive waste must be disposed of through procedures approved by the RSO. No waste is to be washed down drains or otherwise disposed of without prior clearance from the RSO. A copy of the detailed procedures for waste disposal is given in Appendix 6.

Security

All rooms containing radioactive materials or the rooms leading to them must be locked when no trained personnel are present. Furthermore, storage areas, (freezers or refrigerators) containing radioactive materials, should be kept locked except during

periods when trained personnel are present. Storage areas for radioactive waste must be locked at all times.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES

Eating , drinking, smoking	Eating, drinking, smoking or using cosmetics is not permitted in this laboratory.
Wash hands	Wash hands after handling any radioactive material before going about other work.
Pipetting	**Never** pipette anything, even water, by mouth.
Eye wear	Always wear safety glasses in the laboratory. See Chemical Hygiene plan outlining Proteome, Inc. policy.
Protective Clothing	Always use rubber, plastic, latex gloves when handling radioisotopes. protective gloves must be removed before leaving the laboratory to avoid contaminating doorknobs and telephones. Lab coats must be worn in the lab and left in the laboratory. Open toe sandals are not allowed in the laboratory.
Confine the Activity	Always work over trays. Keep and transport radioactive materials doubly contained.
Spills	Notify the Radiation Safety Officer of all spills.
Labeling	Label radioactive material with your name, date, isotope and quantity of isotope.
Before Leaving	Before leaving the laboratory, clean up and monitor your work area and yourself.
*Disposal of **Liquid***	Liquid radioactive materials must be stored in plastic containers or in metal containers if the material is incompatible with plastic. The quantity of isotope, the isotope name, date, and the user's name must be recorded in a log kept with the container. A log is also kept of all liquids disposed of at designated sinks.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES (Con'd)

*Disposal of **Solid***	Solid radioactive waste must be placed in plastic-lined metal boxes or containers. When filled, the contents are transferred to a drum in the waste storage area.
Hoods	Materials which could become airborne must be stored and used in a hood. Hood ventilation shall be left "ON" at all times when containing such materials.
Food	Never keep or store beverages or food in radioisotope labs, in refrigerators or freezers with radioisotopes.

Emergency Procedures

A radiation emergency occurs when a set of circumstances results in hazardous radiation levels, hazardous concentrations of airborne isotopes, or gross contamination of property. Examples of radiation emergencies and actions to be taken are:

a. Personnel Contamination
   1. Remove contaminated clothing.
   2. Wash contaminated skin with mild soap and water. Do not use abrasives.
   3. Call the RSO. After hours, refer to the emergency list.

b. Spill of radioisotope where the radioisotope does not become airborne
   1. Wipe up with absorbent paper using a blotting motion so you do not spread contamination.
   2. Dispose of contaminated paper in radioactive waste container.
   3. Call the RSO. After hours, refer to the emergency list.

c. Volatilization of liquid or dispersal of solid radioisotopes outside a ventilated enclosure
   1. If possible, keep contamination localized by closing doors and restricting access to area. (Do NOT shut off hood.)
   2. Leave the area.
   3. Call the RSO. After hours, refer to the emergency list.

d. Fire in radioisotope area
   1. Treat fire in normal manner.
   2. Call the RSO. After hours, refer to the emergency list.

ALWAYS USE COMMON SENSE IN HANDLING RADIATION EMERGENCIES AND CALL THE RSO AS SOON AS PRACTICAL. DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREA.

PROTEOME, INC.

RADIATION SAFETY OFFICER	Dr. James I Garrels
DAYTIME PHONE:	(508) 922-1643
WEEKENDS AND EVENINGS:	(508) 921-0709 Refer to the emergency call list.

See following page for detailed procedures.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

Emergency Procedures

Be prepared for an emergency by mentally rehearsing the following:

EXTREME HAZARDS

Hazards such as high radiation levels or the possibility of airborne contamination from dry or volatile radioactive materials.

Evacuate	Evacuate the laboratory immediately; close the door and lock it.
Call RSO	Call the RSO immediately. If you have to leave the area to do so, remove your shoes if you suspect contamination and do not touch anything unnecessarily.

OTHER HAZARDS

Hazards such as spills or suspected spills of radioactive material where the material does not become airborne.

Keep calm	Keep calm, use common sense, protect people, do not spread contamination (Always assume you are contaminated until a survey proves otherwise.).
Confine contamination	Localize the spill. Right tipped container. Drop absorbent material on the spill. Damp down a dry spill. Do not track contamination about the laboratory. **If possible, call, do not go for help!** Close door, and where possible adjust the ventilation to prevent spread of airborne material. Check shoes before leaving the area of a cleaned up spill.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

Emergency Procedures

(con'd)

Protect Personnel	Remove contaminated clothing and wash contaminated parts of the body with detergent. Be especially thorough in flushing out wounds. Warn other workers.
Decontaminate	If thorough washing with detergent does not remove contamination from the body, consult the RSO. You will be expected to perform the major work of decontamination of the area of your spill. The RSO will survey for contamination and advise on procedures and assist as necessary All suspected contaminated persons and areas must be monitored after decontamination and before work is resumed.

IN ALL EMERGENCIES, EXCEPT MINOR SPILLS OF RADIOACTIVE MATERIALS, THE RSO MUST BE CALLED AS SOON AS POSSIBLE.

DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

Radioisotope Laboratory Design

The design and furnishings of a laboratory must be commensurate with the hazards presented by the radioisotope and its condition of use. In practical terms some baseline requirements are that:

a. Bench tops or other surfaces on which radioisotopes will be used must either be made of or be covered with a permanently impervious surface.

b. Floors must be covered with an impervious material; properly waxed, vinyl asbestos tiles are normally acceptable.

c. Walls must have a smooth, crack-free and hole-free surface.

d. Proper room ventilation and adequate radioisotope storage must be provided.

APPENDIX 6

SPECIAL PROCEDURES

Monthly Laboratory Survey Procedure

1. Laboratory contamination surveys shall be done on a monthly basis, either by the RSO or an independent consultant.

2. A survey data notebook must be kept, containing layouts of the laboratories, indicating the points at which the wipes were made, and data tables containing the results of the counting of the wipes.

3. Wipes are made using filter paper. Approximately 100 square centimeters of surface should be wiped.

4. Penetrating radiation, e.g., P-32, may be monitored with the GM probe survey instrument.

Radioactive Material Receipt and Opening Procedure

Package Receipt

1. If the shipment appears to be damaged, ask the carrier to remain and immediately proceed to the "Package Opening" procedure below.

2. A contamination survey must be made within three (3) hours after receipt of a radioactive material shipment. Deliveries are accepted only 8 am - 5 pm Monday through Friday. No weekend deliveries.

3. Radioactive material shipments must be separated from the non-radioactive shipments upon receipt. The Radiation Safety Officer and the user must be notified immediately.

Package Opening

1. Wear gloves, a lab coat, badge and safety glasses when preparing to open the package.

2. Using the G-M survey meter, measure the radiation levels at the surface of the container and if necessary at one meter from the surface. Record the results.

3. Wipe the outside shipping container surface and count the wipes to check for contamination.

4. Open the package, and take a wipe of the primary vial containing the radioisotope (or the outside of the package if it is sterile wrapped). Count these and record the results. If there are no counts above background, the container may be discarded in regular trash; otherwise the container must be discarded with solid radiation waste.

5. Record any signs of damage to the package or to the vial.

6. If there is contamination or an excessive radiation level, check the NRC regulations (10CFR20.1906) to see if the NRC or the shipper must be notified.

7. Count the wipes in a Liquid Scintillation Counter.

Delivery of Radioisotope to User

1. Do not leave the package unattended; deliver it immediately to the user so that it may be stored correctly. If the user cannot be found, contact the supervisor of the lab where the delivery was to be made for proper disposition.

SPECIAL PRECAUTIONS FOR WORKING WITH TRITIUM

Procedure involving the handling at any one time of unsealed tritium in amounts exceeding 10 mCi require bioassay. If the tritium is in the form of a nucleotide precursor, bioassay is required for 1 mCi. If the work is performed in a suitable hood bioassay will be required for amounts 10 times those stated above.

The assay is required within 48 hours of processing the above levels of tritium, and then every 2 weeks as long as the individual continues to work with these levels. The sampling frequency may be reduced to quarterly, if after 3 months, the average urinary concentration of specimens obtained during the 3 month period does not exceed 3 uCi/liter.

If urinary excretion rates are found to exceed 5 uCi/liter, an investigation shall be undertaken to determine the cause, and corrective action shall be taken. A repeat assay shall be performed within a week.

If urinary excretion rates exceed 50 uCi/liter, in addition to the above described action, the NRC shall be notified, the case shall be referred therapeutic evaluation, and repeat assays shall be performed approximately weekly until the excretion rate is reduced to 5 uCi/liter.

Handling Procedures for Millicurie Quantities of Phosphorous-32

Phosphorous 32 emits a distribution of energetic beta particles, up to a maximum energy of 1.7 Mev, which can travel as far as 7 meters in air. The absorbed dose rate close to containers of millicurie quantities of P-32 is on the order rads/min. A significant fraction of P-32 entering the body deposits in the bone structure. The annual limit of intake is 540 microcuries.

The following procedures should offer a guide to using sources of P-32 in excess of one millicurie.

1. Prepare a written set of procedures and submit them to the RSO for approval prior to the run.

2. Avoid handling the vial directly. Use remote handling tools, such as tongs or special holders when handling the source containers.

3. Use low density shielding (e.g. a minimum of **0.3** in of plexiglas) to absorb the beta particles without generating significant amounts of X-rays by an interactive process called Bremsstrahlung. Heavy materials (high atomic number) must not be used close to the source because the Bremsstrahlung process is much more efficient for these materials. However, a small amount of lead on the outside of a plastic shield will absorb the Bremsstrahlung X-rays efficiently.

4. Always wear safety glasses to protect eyes from splashes and unnecessary radiation when working with radioactive materials.

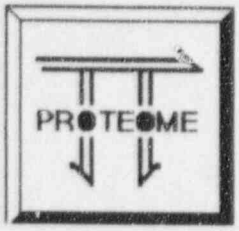
5. Wear two sets of gloves; strip the outer pair off and replace if they become contaminated. Keep the inner pair clean at all times.

6. Have immediately available a properly operating GM survey meter for use in detecting contamination and radiation fields. Surveys must be done during the procedure to evaluate the dose to the experimenter and after to check for personal contamination and bench top contamination.

7. Wear personal dosimeter and finger dosimeters. The finger dosimeters are important because they will monitor the dose given to the fingers which the body dosimeter will not see.

8. Have your supervisor or the RSO observe during your first procedure.

9. After each procedure, survey the area to check for contamination.



Proteome, Inc.

Radioisotope Receipt and Delivery

Radioisotope Ordered: _____ Activity Ordered: _____

Radioisotope Received: _____ Activity Received: _____

P.O. #: _____

Location of Use:_____

Contamination Survey

Counts per minute over 100 cm^2 area: _____cpm

Efficiency of counting instrument: _____%

Contamination level (dpm) = cpm / effic. = _____dpm

Contamination level (μCi) _____dpm / 2.22 x 10^6 d/μCi = _____μCi

For All Packages:

Radiation Levels at Surface (mR/hr): _____

Radiation Levels at 1 Meter (mR/hr): _____

Acceptable levels	'1 Red Bar' package	0.5 mR/hr at surface	background at 1 meter
	'2 Red Bars' package	50 mR/hr at surface	1 mR/hr at 1 meter
	'3 Red Bars' package	200 mR/hr at surface	10 mR/hr at 1 meter

Packages above acceptable limits are held for notification to vendor, shipper, and NRC. Contact the RSO immediately.

Date and Time of Delivery to User: _____

Radioactive Waste Inventory

Disposed of empty container: _____User: _____

Date	Radioisotope	Activity	User

TOTALS: (To be completed when the radioactive waste is shipped.)

Radioisotope	Total Activity (mCi)

COLLECTION AND DISPOSAL OF RADIATION WASTE

Radioactive waste must be collected, packaged, transported, stored, and disposed or in accordance with NRC regulations. To assure compliance with these regulations, all waste must be handled according to the following instructions.

Liquid Radioactive Waste: Proteome, Inc. is allowed to dispose of liquid radioactive waste into the sanitary sewage system in accordance with 10 CFR 20.2003 provided the liquids are readily soluble in water and biologically miscible. The Proteome, Inc. procedures and limits for sink disposal of liquid radiative waste are given in Section I of Appendix VI of the Radiation Safety Guide.

Isotopes with half-lives less than 90 days: The procedures given in Section 2, Appendix VI of the Radiation Safety Guide assure that Proteome, Inc. is permitted to store waste generated by isotopes with half-lives less than 90 days on-site until decay to background (a minimum of 10 half-lives).

Waste generated in this category must be segregated at the point of collection, according to nuclide.

Isotopes with half-lives greater than 90 days: The procedures given in Section 3, Appendix VI of the Radiation Safety Guide assure that Proteome, Inc. is permitted to store 3-H and 14-C waste on-site prior to disposal by a licensed shipper.

If you have any questions, please talk to your supervisor or the RSO.

INSTRUCTIONS FOR EMPLOYEES

Waste minimization: Make sure that you adhere to the radiation waste minimizaation policy. Plan your experiments carefully and monitor the waste you generate and segregate radioactive from non-radioactive waster as it is generated.

For liquid waste, make sure the waste is readily soluble in water and that the limits for sink disposal per month have not been exceeded. Log each disposal on the log forms provided in the disposal area.

For liquid waste that is not water soluble, absorb the waste into the container provided and dispose as solid waste according to the number of the isotope.

For solid waste, clear plastic bags have been provided. When full, the bags must be fastened closed, affixed with a "caution-radioactive materials" tag, specifically noting the nuclide, the date, the activity, and the identity of the employee who completed the

tag. The bag should then be placed within one of the labeled barrels located in the laboratory. There is a designated barrel specific for each nuclide-generated waste. All radiation labels shall be removed or obliterated prior to waste being placed in plastic bags.

Please notify the RSO when barrels are full and need to be moved to the Radiation Waste Storage Room.

****Special Handling Procedures for 35-S and 33-P Waste****

- Individual plastic bags must contain no more than a maximum activity of 100uCi.
- When 3/4 full, individual plastic bags must be fastened closed such that there is enough empty space to safely "flatten" it (to increase surface area and decrease density) as it is placed into storage barrel. 35-S and 33-P are weak beta emitters. This procedure will facilitate detection of radioactivity above background at the end of 10 half-life storage.

Failure to comply with these instructions will result in the suspension of nuclide purchasing privileges.

WASTE DISPOSAL PROCEDURES

1. Disposal of Liquid Radioactive Waste into Sanitary Sewage System

Liquid radioactive waste will be disposed of in the sanitary sewage system in accordance with 10 CFR 20.2003 and the applicable concentration in Appendix B Table II. All liquids disposed in this manner will be readily soluble in water and biologically miscible as determined from Material Safety Data Sheets, the Handbook of Chemistry and Physics, and other regulatory guidelines. Any liquids that cannot meet these guidelines will be absorbed and disposed of as low level radioactive waste.

The Proteome maximum limits listed below are based on ALARA and are well within NRC maximum calculated limits which are based on a total sanitary outflow at 5 E +8 cc/month and the allowable concentrations listed in Appendix B of 10 CFR 20.

Allowable Concentrations uCi/cc (App. B)		Maximum **Calculated** Monthly Limits (in mCi)	Maximum **ALARA** Monthly Limits (in mCi)
3-H	1E-2	5000	50**
14-C	3E-4	150	7.5*
35-S	1E-3	500	50***
32-P	9E-5	45	4.5***
33-P	8E-4	400	40***

*Based on ALARA set at 5%.
**Based on ALARA set at 1%.
***Based on ALARA set at 110%.

In no case shall the annual totals of liquid effluent radioactive wastes exceed 5 Ci of 3-H, 1 Ci of 14-C, and 1 Ci of all other isotopes combined and in no case shall the monthly sum of the fractions of each nuclide disposed of in this way exceed unity. Records will be maintained to document compliance with NRC regulations and will be used to monitor monthly outflow volumes via the sanitary sewage system. The RSO

will periodically reaffirm and may, at his discretion, modify (increase or decrease) the maximum allowable monthly limits to maintain compliance with 10 CFR Part 20.2003.

Amounts disposed of must be recorded accurately and at the time of disposal, at the sink and the total per sink per month cannot exceed unity (i.e. 50% of daily limit for ^{32}P and no more than 50% of daily limit for ^{35}S).

If the aqueous waste is significantly higher than the daily limits, they can be stored in separate containers (separated by isotope).

2. Decay-in-Storage Program for solid radioactive waste with half-lives of less than 90 days.

   Solid wastes will be put into plastic bags, with a separate bag for each isotope. Bags will be labeled by nuclide, date, activity, and name of employee completing the page. These bags containing nuclides with half life less than 90 days will be placed in the radioactive waste storage room and stored for 10 half-lives. The bags will each contain a maximum of 100 uCi when placed in the decay-in-storage containers.

   When 3/4 full, each plastic bag containing 35-S or 33-P will be fastened closed such that there is enough empty space to safely "flatten" it (to increase surface area and decrease density) as it is placed into storage barrel. (Given that 35-S and 33-P are weak beta emitters, this procedure should facilitate detection of radioactivity above background at the end of 10 half life storage.) Each bag will be labeled with a "caution-radioactive materials" tag specifically noting the nuclide, the date, the activity, and the identity of the employee who completed the tag.

   When the labeled bags are moved to the Radiation Waste Storage Room, the tags will be affixed to the barrels in which the waste is placed for storage and tags will be cosigned by the RSO (or his designate) as the bags are placed into the barrels. Duplicte copies will be maintained by the RSO. Log sheets taped to each barrel will maintain a running record of the contents as bags of waste are added to each barrel, including date(s) of placement and accumulating activity.

   As each barrel becomes full, it will be sealed closed and, based upon the information on the Log Sheet for that barrel, the "OUT" date will be calculated as the earliest future date by which a minimum of 10 half-lives will have elapsed based upon the most recent (i.e. the last) bag of waste added to the barrel prior to its being closed. At the time the barrel is closed, a duplicate copy of the log sheet will be made and placed in the RSO files.

At the end of the 10 half-life storage period, the barrel will be surveyed using a pancake GM probe. The bags containing 35-S and 33-P will be flattened and given a preliminary survey. If a dose rate is detected, the barrel will be returned to storage. If there is no radioactivity above background, the barrel will be removed to an area in the facility where background radiation is low. Each plastic bag will be opened and the contents spread for survey using a pancake GM probe. With a background count of approximately 40 cpm, it is possible to detect 1.5 x background or 20 net cpm. Thus if we find a hot spot and count for a minute an efficiency of about 15%, we will be able to detect 6E-5 uCi/cpm. By counting for a full minute we are able to minimize the standard deviation at the 95% confidence level to 1.2E-4 uCi.

3. Storage and Disposal for Long Lived Radioactive Waste

Proteome, Inc. will follow the guidelines as established by the Nuclear Regulatory Commission in Information Notice 90.09.

The format below follows the outline found in NRC information Notice 90-09 and is on file with the RSO.

1. Identification of waste to be stored.

   a. It will not be necessary to increase the possession limits for extended interim storage of Low Level Waste. The possession limits have been determined to compensate for this problem with the submission of the application.

   b. Not to exceed 7.5 cubic feet per year. At most, millicurie quantities of tritium and carbon-14.

   c. All waste is CLASS A. All stored waste is solid. It is Proteome, Inc.'s policy to employ volume reduction through compaction and planned waste avoidance. The material stored will have no additional non-radiological properties.

   d. N/A

   e. The storage will not necessitate any additional permits.

2. Final Disposal Policy and Plan

   a. Long-lived waste will be shipped to a low level waste site by a licensed shipper such as ADCO.

3. Physical Description of Storage Area

a. A plan identifying the location and size of the Storage Area is part of ATTACHMENT II of this application. Visual inspection and access to the drums by authorized personnel will be non-problematic. Air sampling will be conducted by portable air sampler in the room, if at all necessary. No volatiles will be in the room.

b. Maximum storage capacity is four 55 gallon steel drums, which is one drum per year for the decay-in-storage plan and one drum for long-lived waste. This will be a deposit storage based on current projections.

c. Waste storage is internal to the leased space and protected from the weather at all times.

d. The waste storage facility will be locked at all times with keys or card access controlled by the RSO.

e. General room air ventilation will be designed to operate properly and will be adequate for this type of waste.

f. The storage of the company waste will be in a room equipped and protected by the base building sprinkler system.

g. N/A

h. N/A

4. Package and Container Integrity

a. Proteome, Inc.'s policy will be to package long-lived radioactive waste in 55 gallon steel drums which are currently the accepted packaging for transportation and final disposal. The waste shall be such to pose no hazard to the integrity of the container and the container should last indefinitely.

b. Routine radiation monitoring shall be done in the storage area along with visual inspection of the stored containers.

c. N/A

5. Radiation Protection

a. The plan will call for the storage of tritium and carbon-14. There will be no radiation dose rates from the storage containers. Weekly calibrated surveys of the storage area will be done. The door to the area will be posted with the appropriate "Caution Radioactive Material" sign in accord with 10-CFR-20.1902.

b. The radionuclides and the activities to be used will not generate any dose rates and thus special shielding will not be required. Special personnel monitoring will not be necessary.

c. The name and home telephone number of the RSO will be posted on the door. The emergency procedures adopted are part of our OSHA required Chemical Hygiene Plan.

d. All drums will be appropriately labeled with the required information about the drums contents. Each bag of waste placed in storage will have a radioactive materials tag with the radionuclide, amount, date of packaging, and the person responsible for generating the waste. **[A running record will be kept on each barrel with an outdate when the ten half lives have transpired.]** A log will be maintained of the activity at any time.

6. Proteome, Inc.'s policy requires all workers handling radioisotopes including waste to attend our radiation worker training seminars which include instruction on waste minimization, packaging, handling, radiation survey techniques, and emergency procedures.

7. Financial Assurance

   a. The proposed limits in the application do not require posting of financial assurance.

8. Emergency Plan

   a. Our proposed possession limits requested at this time in this application do not require an emergency plan per 30.32 (i)(1).

NRC FORM 577 (1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

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

PROTEOME, INC.
ATTN: JAMES I. GARRELS, PH.D.
200 CUMMINGS CENTER
SUITE 425C
BEVERLY, MA 01915

*EFFECTIVE DATE FOR NEW FEES WAS 6/11/96, YOUR REQUEST WAS RECEIVED 6/5/96, THEREFORE, THE OLD FEE IS APPROPRIATE.

TYPE OF ACTION

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

REQUESTED DATE: 5-31-96

LICENSE NUMBER: NEW

CONTROL NUMBER: 123297

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
3M	$ 1,500.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

* FEE(s) DUE	$ 1,500.00
PAYMENT RECEIVED	$ 1,400.00
AMOUNT DUE	$ 100.00

- [X] Your request was received without the prescribed application fee.
- [X] We received your Check No. 1267 in the amount of $ 1,400.00. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license 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

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] 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 license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
BRENDA BROWN	BB	
	6/13/96	

Distribution: DENNING File
MAF Correspondence FY
LFDCB Chief
LFDCB Analyst
Invoice File w/encl
LFDCB R/F (2)
DAF R/F
DC/DAF/SF (LF-3-2-9)

DATE: 6-13-96

4

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

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

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: PROTEOME, INC.
RECEIVED DATE: 960605
DOCKET NO: 3034169
CONTROL NO.: 123297
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $1400.00
CHECK NO.: 1267

3. COMMENTS

SIGNED M. A. Perkins
DATE 6/5/96

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

1. FEE CATEGORY AND AMOUNT: 3M $1400

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

3. OTHER ---

SIGNED Bruce B.
DATE 7/1/96

96 JUN 11 A8:00

IAP
Log June 8
Remitter
Check No. 1267 1522
Amount $1,400 $400
Fee Category 3M
Kind of Fee APP
Check Rec'd 7/1/96
Completed
By BBrown