NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION



# MATERIALS LICENSE

Amendment No. 25

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.

398510

| Licensee | |
|---|---|
| 1. Blood Center of Southeastern Wisconsin<br>2. P.O. Box 2178<br>Milwaukee, WI 53201-2178 | In accordance with application dated April 27, 1995<br>3. License Number 48-02000-01 is renewed in its entirety to read as follows:<br>4. Expiration Date November 30, 2001<br>5. Docket or Reference No. 030-03424 |

| 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. 250 millicuries |
| B. Carbon-14 | B. Any | B. 25 millicuries |
| C. Phosphorus-32 | C. Any | C. 50 millicuries |
| D. Sulfur-35 | D. Any | D. 100 millicuries |
| E. Calcium-45 | E. Any | E. 5 millicuries |
| F. Chromium-51 | F. Any | F. 300 millicuries |
| G. Iron-59 | G. Any | G. 20 millicuries |
| H. Iodine-125 | H. Any | H. 200 millicuries |
| I. Iodine-131 | I. Any | I. 50 millicuries |
| J. Mercury-203 | J. Any | J. 10 millicuries |
| K. Chromium-51 | K. As included in 10 CFR 35.100 | K. 300 millicuries |

9. Authorized Use:

A. through J. To be used for <u>in vitro</u> studies and research and development as defined in 10 CFR Part 30, Section 30.4.

K. To be used for medical use described in 10 CFR 35.100.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-02000-01

Docket or Reference Number
030-03424

Amendment No. 25

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at 638 North 18th Street, Milwaukee, Wisconsin and 8727 Watertown Plank Road, Milwaukee, Wisconsin.

B. Licensed material may be stored at the licensee's facilities located at 1725 West Wisconsin Ave., Milwaukee, Wisconsin.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

| Authorized Users | Material and Use |
|---|---|
| Richard H. Aster, M.D. | All |
| Therese Wiedmer, Ph.D. | All, except 35.100 material |
| Robert R. Montgomery, M.D. | All, except 35.100 material |
| Nancy A. Drzewiecki | All, except 35.100 material |
| David D. Eckels, Ph.D. | All, except 35.100 material |
| Jack A. Gorski, Ph.D. | All, except 35.100 material, Iodine-125 and Iodine-131 involving radioiodination |
| Peter J. Newman, Ph.D. | All, except 35.100 material |
| John Paul Scott, M.D. | All, except 35.100 material and Phosphorus-32 |
| Nancy J. Schunk | All, except 35.100 material |
| Debra Endean, Ph.D. | All, except 35.100 material |
| Joan C. Gill, M.D. | All, except 35.100 material |
| Daniel B. Bellissimo, Ph.D. | All, except 35.100 material |
| Janice G. McFarland, M.D. | All, except 35.100 material |
| Peter J. Sims, M.D., Ph.D. | All, except 35.100 material |
| Gian P. Visentin, M.D. | All except 35.100 material |

| Authorized Users | Material and Use |
|---|---|
| Philip Kroner, Ph.D. | All, except 35.100 material |
| James A. Augustine, Ph.D. | All, except 35.100 material |
| Cheryl A. Hillery, M.D. | All, except 35.100 material |
| Debra K. Newton-Nash, Ph.D. | All, except 35.100 material |

12. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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

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

    B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter 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 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.

14. The Radiation Protection Officer for the activities authorized by this license is Nancy A. Drzewiecki.

15. The licensee shall conduct sampling and analysis of effluents from iodination hoods to demonstrate compliance with the provisions of 10 CFR 20.1301. The effluent sampler filter media shall have a retention efficiency for elemental iodine of greater than 99 percent. Records of evaluations shall be retained for review by the Commission.

**MATERIALS LICENSE**
**SUPPLEMENTARY SHEET**

License Number
48-02000-01

Docket or Reference Number
030-03424

Amendment No. 25

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

A. Application dated April 27, 1995; and

B. Letters dated September 5, 1996, and October 4, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 11/5/96

By Kevin G. Null
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02410
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 19950531
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: BLOOD CTR. OF SOUTHEASTERN WISC
RECEIVED DATE: 950428
DOCKET NO: 3003424
CONTROL NO.: 398510
LICENSE NO.: 48-02000-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: $1400
CHECK NO.: 715393

3. COMMENTS

SIGNED [signature]
DATE 5-1-95

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

1. FEE CATEGORY AND AMOUNT: 7C $1400.00

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

3. OTHER

SIGNED SC
DATE 5/3/95

RECEIVED
MAY 08 1995
REGION III

95 MAY -3 PM 2:02

Log May 2 III
Remitter
Check No. 715393
Amount $1400.00
Fee Category 7C
Type of Fee Renewal
Date Check Rec'd 5/3/95
Date Completed
By: SC

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

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

# APPLICATION FOR MATERIAL LICENSE

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

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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

**APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

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

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**

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

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

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

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

**IF YOU ARE LOCATED IN:**

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

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

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

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

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 48-02000-01

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

The Blood Center of Southeastern
Wisconsin, Inc.
P.O. Box 2178
Milwaukee, Wisconsin 53201-2178

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

638 North 18th Street
Milwaukee, Wisconsin 53233

8737 Watertown Plank Road
Milwaukee, Wisconsin 53226

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Nancy J. Schunk

TELEPHONE NUMBER
(414) 937-6225

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7C
AMOUNT ENCLOSED $1400.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

| CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE |
|---|---|---|
| Richard E. Limbach, Executive Vice President & COO | Richard E. Limbach | 4/27/95 |

## FOR NRC USE ONLY

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

RECEIVED
APR 28 1995
REGION III

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

398 SD

The Blood Center
of Southeastern Wisconsin

April 27, 1995

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Renewal of License Number 48-02000-01

Dear Sir or Madam:

Enclosed is our renewal application for NRC Materials License 48-02000-01, issued to The Blood Center of Southeastern Wisconsin, Inc., and a check for the renewal fee of $1400.00.

In the application, you will note that our facility address has changed. This change does not represent a new location for our establishment. It is only a change in our address because remodeling at our facility is changing the main entrance from Wisconsin Avenue to 18th Street.

| Mailing Address | Facility Address |
|---|---|
| P.O. Box 2178 | 638 North 18th Street |
| Milwaukee, Wisconsin 53201-2178 | Milwaukee, Wisconsin 53233 |

If you have any questions regarding this submission, please do not hesitate to contact me at (414) 937-6225.

Sincerely,

Nancy J. Schunk

Nancy J. Schunk
Radiation Safety Officer
Manager, Quality Assurance
and Safety

Enclosures



1701 West Wisconsin Avenue
Milwaukee, Wisconsin 53233-2194
(414) 933-5000
FAX: (414) 937-6332

**5. RADIOACTIVE MATERIAL.**

| Element and Mass Number | Chemical and/or Physical Form | Maximum Amount Which Will Be Possessed At Any One Time |
|---|---|---|
| Hydrogen-3 | Any | 250 millicuries |
| Carbon-14 | Any | 25 millicuries |
| Phosphorus-32 | Any | 50 millicuries |
| Sulfur-35 | Any | 100 millicuries |
| Calcium-45 | Any | 5 millicuries |
| Chromium-51 | Any | 300 millicuries |
| Iron-59 | Any | 20 millicuries |
| Indium-111 | Any | 30 millicuries |
| Iodine-125 | Any | 200 millicuries |
| Iodine-131 | Any | 50 millicuries |
| Mercury-203 | Any | 10 millicuries |

## 6. PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED.

The radioisotopes listed in Item 5 will be used in biomedical research and diagnostic clinical laboratories working with blood and blood components. Isotopes are used for *in vitro* studies except as noted below. Typical examples of use are:

a) Metabolic studies of leukocytes and endothelial cells using hydrogen-3 and sulfur-35 labeled nucleotides.

b) Radiolabeling plasma proteins, cell surface proteins on platelets, and monoclonal and polyclonal antibodies with iodine-125 and iodine-131.

c) Lysis assays of chromium-51 labeled lymphocytes, red cells and platelets.

d) Genetic and protein sequencing using phosphorus-32 and sulfur-35 labeled DNA and RNA.

Chromium-51, as sodium chromate, will also be used for *in vivo* red blood cell and platelet survival studies. This use will be under the direction of Richard H. Aster, M.D., who is currently licensed to use materials specified in 10 CFR 35.100 and who has been authorized for this use in NRC license number 48-02000-01 since June 12, 1970. His training and experience is detailed in Item 8.

## 7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

Radiation Safety Officer

Nancy J. Schunk is the Radiation Safety Officer (RSO) responsible for implementing The Blood Center's radiation safety program, including those responsibilities detailed in 10 CFR 35.21. The Blood Center Radiation Safety Committee will delegate authority to the RSO for enforcement of the radiation safety program designed to assure that occupational doses and doses to members of the public are as low as reasonably achievable (ALARA) and will support the RSO in those instances where it is necessary for the RSO to assert her authority. Ms. Schunk's training and experience is detailed in Item 8.

Radiation Safety Staff

The RSO is assisted in the daily operations of the radiation safety program by Nancy A. Drzewiecki, Supervisor of Occupational Health and Safety, and Mary L. Pawlak, Supervisor of Research Lab Operations.

Radiation Safety Committee

The Blood Center has established a Radiation Safety Committee (RSC) to oversee the radiation safety program and will provide sufficient authority, organizational freedom, and management prerogative to identify radiation safety problems; initiate, recommend, or provide corrective actions; and verify implementation of corrective actions. Responsibilities of the RSC include, but are not limited to, those items detailed in 10 CFR 35.22.

The following is the minimum roster of The Blood Center Radiation Safety Committee. Other members-at-large may be added to complement the expertise of the committee at the discretion of the Chairman.

a) Peter J. Newman, Ph.D., an Authorized User whose training and experience is detailed in Item 8, will serve as Chairman of the Radiation Safety Committee.

b) Nancy J. Schunk is Radiation Safety Officer.

c) Richard E. Limb[illegible]h, Executive Vice President and Chief Operating Officer of The Blood Cente[illegible]ill serve as Administration Representative.

d) Research Laboratory Representative.

e) Clinical Laboratory Representative.

f) Facilities Management Representative.

## 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

All new or transferred employees working with radioactive materials or new or transferred employees who, in the course of their duties, will frequent areas where radioactive materials are used, are given instruction about The Blood Center's Radiation Safety program at a level appropriate to their duties, including, but not limited to, the material specified in 10 CFR 19.12. In addition, all personnel receiving Radiation Safety training as a new or transferred employee are instructed as specified in 10 CFR 19.12 annually. A copy of the handout provided during initial training to employees who work with radioactive materials is attached (Appendix A).

Individuals working with radioisotopes in laboratories work under the immediate supervision of the Authorized Users listed below. Responsibilities of the Authorized Users include those items detailed in 10 CFR 35.25, as well as those outlined in The Blood Center's ALARA Program.

Richard H. Aster, M.D. - OK
James A. Augustine, Ph.D. OK
Daniel B. Bellissimo, Ph.D. — ?
Nancy A. Drzewiecki — ?
David D. Eckels, Ph.D. - OK
Debra Endean, Ph.D. - OK
Paul Foster, M.D. - OK
Joan C. Gill, M.D. - OK
Amy Goldberger, Ph.D. - OK
Jack Gorski, Ph.D. - OK
Cheryl A. Hillery, M.D. - OK
Philip Kroner, Ph.D. - OK
Janice G. McFarland, M.D. - OK
Robert R. Montgomery, M.D. - OK
Peter J. Newman, Ph.D. - OK
Debra Newton-Nash, Ph.D. - OK
Nancy J. Schunk - OK
J. Paul Scott, M.D. - OK
Peter J. Sims, M.D., Ph.D. - OK
Gian P. Visentin, M.D. ?
Therese Wiedmer, Ph.D. - OK

Training and experience resumes for the Authorized Users are detailed on pages 6 - 26.

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Richard H. Aster, M.D.

**Education:** B.S., Physics and Mathematics, June 1951
M.D., Hematology, June 1957
Licensed to practice Medicine in Wisconsin

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Michigan, Ann Arbor, MI
Cyclotron Project, 2 years; Lecture/Lab courses, 40 hours;
Supervised Lab Experience, 400 hours
Harvard University, Cambridge, MA
Lecture/Lab courses, 8 hours

*Field:* *Radiation Protection*
University of Michigan, Ann Arbor, MI
Degree in Physics
Harvard University, Cambridge, MA
Lecture/Lab courses, 8 hours

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Michigan, Ann Arbor, MI
Courses in Nuclear Physics, 40 hours

*Field:* *Radiation Biology*
Harvard University
Lecture/Lab courses, 8 hours

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{131}I$ | 5 mCi | University of Michigan | 2 years | Med. Invest. |
| $^{128}I$ | 1 mCi | University of Michigan | 1 year | Med. Invest. |
| $^{125}I$ | 1 mCi | Harvard University | 3 years | Med. Invest. |
| $^{51}C$ | 5 mCi | Harvard University & Blood Center of Southeastern WI | 25 years | Med. Invest.; Research |
| $^{14}C$ | 5 mCi | Harvard University | 2 years | Med. Invest. |
| $^{3}H$ | 500 mCi | Blood Center of Southeastern WI | 5 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** James A. Augustine, Ph.D.

**Education:** B.S. in Pharmacy, 1978
Ph.D. in Pharmacology, 1987

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
University of Pittsburgh, PA, 1983-1984
Laboratory Work, 1 year

Mayo Clinic, Rochester, MN, 1988-1992
Laboratory Work, 4 years

*Field:* *Radiation Protection*
Mayo Clinic, Rochester, MN, 1988
Lecture in Radiation Protection, 1 hour

*Field:* *Radiopharmaceutical Chemistry*
University of Pittsburgh, PA, 1977
Course in Radiopharmaceutical Chemistry, 6 hours

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 1 mCi | Mayo Clinic, Rochester, MN | 2 years | Research |
| $^{3}H$ | 5 mCi | Mayo Clinic, Rochester, MN | 3 years | Research |
| $^{35}S$ | 15 mCi | Mayo Clinic, Rochester, MN | 4 years | Research |
| $^{32}P$ | 20 mCi | Mayo Clinic, Rochester, MN | 4 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Daniel B. Bellissimo, Ph.D.

**Education:** B.S. in Biochemistry, 1980
Ph.D. in Biochemistry, 1988

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Wisconsin-Madison, 1977 - 1978
Courses in Physics, 5 credit hours x 2

*Field:* *Radiation Protection*
Duke University, 1981 - 1987
Radiation Safety Training, 1 hour x 6
Ciba-Geigy, 1988 - 1991
Radiation Safety Training, 1 hour x 4
The Blood Center of Southeastern Wisconsin
Radiation Safety Training, 1 hour x 2

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Wisconsin-Madison, 1977 - 1978
Courses in Calculus, 5 credit hours x 3

*Field:* *Radiation Biology*
Duke University, 1981 - 1987
Radiation Safety Training, 1 hour x 6
Ciba-Geigy, 1988 - 1991
Radiation Safety Training, 1 hour x 4
The Blood Center of Southeastern Wisconsin
Radiation Safety Training, 1 hour x 2

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 1 mCi | Duke University | 6 years | Research |
| $^{32}P$ | 1 mCi | Duke University | 6 years | Research |
| $^{14}C$ | 500 µCi | Duke University | 2 years | Research |
| $^{3}H$ | 500 µCi | Ciba-Geigy, Research Triangle Park, North Carolina | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Nancy A. Drzewiecki

**Education:** B.S. in Molecular Biology/Biochemistry, May 1991

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Wisconsin-Milwaukee, Milwaukee
Marquette University, Milwaukee
Courses in Physics, Analytical Chemistry and Physical Chemistry, 3 hours x 6

*Field:* *Radiation Protection*
Marquette University, Milwaukee
Medical College of Wisconsin, Milwaukee
The Finch University of Health Sciences/The Chicago Medical School
The Blood Center of Southeastern Wisconsin, On-the-Job Training

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Wisconsin-Milwaukee, Milwaukee
Calculus courses, 3 hours x 4

*Field:* *Radiation Biology*
Medical College of Wisconsin, Milwaukee
The Finch University of Health Sciences/The Chicago Medical School
The Blood Center of Southeastern Wisconsin, On-the-Job-Training

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{32}P$ | 10 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{35}S$ | 4 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{125}I$ | 20 mCi | Medical College of Wisconsin | 1 year | Research |
| | | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{3}H$ | 2 mCi | Medical College of Wisconsin | 1 year | Research |
| | | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{51}Cr$ | 5 mCi | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{14}C$ | 1 mCi | Blood Center of Southeastern WI | 1 year | Radiation Safety |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: David D. Eckels, Ph.D.

**Education:** M.A. in Microbiology, December 1977
Ph.D. in Immunology, October 1979

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of California, Davis, 1976-1979
12 hours lecture/lab courses; 2 hours supervised lab experience

*Field:* *Radiation Protection*
University of California, Davis, 1976-1979
12 hours lecture/lab courses; 2 hours supervised lab experience

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of California, Davis, 1976-1979
12 hours lecture/lab courses; 2 hours supervised lab experience

*Field:* *Radiation Biology*
University of California, Davis, 1976-1979
12 hours lecture/lab courses; 6 hours supervised lab experience

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{3}H$ | 15 mCi | University of California - Davis | 3 years | Research |
| | 15 mCi | Georgetown Univ. School of Medicine | 5 years | Research |
| | 15 mCi | Blood Center of Southeastern WI | 5 years | Research |
| $^{51}Cr$ | 10 mCi | University of California - Davis | 3 years | Research |
| | 10 mCi | Georgetown Univ. School of Medicin. | 5 years | Research |
| | 10 mCi | Blood Center of Southeastern WI | 5 years | Research |
| $^{14}C$ | 5 mCi | Blood Center of Southeastern WI | 2 years | Research |
| $^{125}I$ | 5 mCi | Blood Center of Southeastern WI | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Debra J. Endean, Ph.D.

**Education:** B.A. in Biology/French Literature, May, 1979
Ph.D. in Genetics, August, 1986

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
Lake Forest College, IL, 1975-1979
Physics Course with Lab, 1 year

*Field:* *Radiation Protection*
University of Wisconsin-Madison, 1979-1986
Northwestern University, IL, 1986-1988
The Blood Center of Southeastern Wisconsin, 1989-present
Supervised laboratory experience

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Lake Forest College, IL, 1975-1979
Calculus, 1 semester

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{32}P$ | 2 mCi | U.W.-Madison, Northwestern U., Blood Center of Southeastern WI | 15 years | Research & Clinical Testing |
| $^{3}H$ | 250 µCi | U. of Wisconsin, Madison | <1 year | Research |
| $^{35}S$ | 500 µCi | Northwestern University | <1 year | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Paul A. Foster, M.D.

**Education:** B.S. in Chemistry, 1976
M.D. in Internal Medicine, 1983
M.D. in Hematology, 1988
Licensed to Practice Medicine in Wisconsin, California, and North Carolina

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
University of Michigan, 1972-1976
40 hours of Course/Laboratory Work

*Field:* *Radiation Protection*
Duke University, School of Medicine, 1976-1980
9 hours of Course/Laboratory Work

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Michigan, 1972-1976
University of North Carolina, 1983-1984
24 hours of Course/Laboratory Work

*Field:* *Radiation Biology*
Duke University, School of Medicine, 1976-1980
21 hours of Course/Laboratory Work

*Field:* *Radiopharmaceutical Chemistry*
Duke University, School of Medicine, 1976-1980
60 hours of Course/Laboratory Work

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 4 mCi | Scripps Clinic & Research Foundation | 5 years | Research |
| $^{3}H$ | 2 mCi | Duke University, Durham, N.C. | 2 years | Research |
| $^{32}P$ | 2 mCi | Scripps Clinic & Research Foundation | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Joan C. Gill, M.D.

**Education:** B.S. in Biology, May 1965
M.D., Medicine, May 1972
Pediatrics, June 1980
Pediatric Hematology/Oncology, October 1982
Licensed to practice Medicine in Wisconsin

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of IL, Physics course, 1 semester
University of WI, Physics course, 1 semester
Medical College of WI, 1 month, 1980

*Field:* *Radiation Protection*
University of IL, Physics course, 1 semester
University of WI, Physics course, 1 semester
Medical College of WI, 1 month, 1980

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of IL, Physics course, 1 semester
University of WI, Physics course, 1 semester
Medical College of WI, 1 month, 1980

*Field:* *Radiation Biology*
University of IL, Physics course, 1 semester
University of WI, Physics course, 1 semester
Medical College of WI, 1 month, 1980

*Field:* *Radiopharmaceutical Chemistry*
University of IL, Physics course, 1 semester
University of WI, Physics course, 1 semester
Medical College of WI, 1 month, 1980

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{131}I$ | | University of Wisconsin | 2 years | *in vivo* Studies |
| $^{59}Fe$ | | University of Wisconsin | 2 years | *in vivo* Studies |
| $^{51}Cr$ | 5 mCi | University of Wisconsin<br>Blood Center of Southeastern WI | 3 years | *in vivo* Studies<br>Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Amy Goldberger, Ph.D.

**Education:** B.A. in Biology, June 1979
Ph.D. in Biochemistry, December 1983

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
Univ. of TN, Knoxville, 1978-1979
Physics Course with Lab

*Field:* *Radiation Protection*
Vanderbilt University, 1982
Radiation Safety Course

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Rhodes College, Univ. of TN, 1975-1976
Calculus courses

Vanderbilt University, 1979-1983
Biochemistry and Radiation Safety courses

*Field:* *Radiation Biology*
Rhodes College, 1975-1976
Biology course & Labs

Vanderbilt University, 1982
Radiation Safety

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{3}H$ | 2 mCi | Mayo Clinic | 4 years | Research |
| | 5 mCi | Univ. of MA School of Medicine | 1½ years | Research |
| | 5 mCi | Blood Center of Southeastern WI | 1 year | Research |
| $^{32}P$ | 500 µCi | Univ. of MA School of Medicine | 1½ years | Research |
| $^{125}I$ | 5 mCi | Blood Center of Southeastern WI | 6 months | Research |
| $^{35}S$ | 5 mCi | Blood Center of Southeastern WI | 6 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Jack Gorski, Ph.D.

**Education:** B.S. in Chemistry, June 1971
Ph.D. in Developmental Biology, June 1976

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Cincinnati, 1972
AEC course, 6 hours

*Field:* *Radiation Protection*
University of Cincinnati, 1972
AEC course, 6 hours

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Cincinnati, 1972
AEC course, 6 hours

*Field:* *Radiation Biology*
University of Cincinnati, 1972
AEC course, 6 hours

University of Geneva, Dept. of Microbiology, 1982
Radiation Safety course, 2 hours

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{32}P$ | 60 mCi | U. Cincinnati, Dept. of Biochem. | 3 years | Research |
| | 1 mCi | U. of Geneva, Microbiology | 9 years | Research |
| | 1 mCi | Blood Center of Southeastern WI | 12 years | Research |
| $^{3}H$ | 1 mCi | U. of Geneva, Microbiology | 9 years | Research |
| $^{125}I$ | 0.5 mCi | U. of Geneva, Microbiology | 2 years | Research |
| $^{14}C$ | 1 mCi | U. of Geneva, Microbiology | 9 years | Research |
| $^{35}S$ | 0.5 mCi | U. of Geneva, Microbiology | 2 years | Research |
| | 1 mCi | Blood Center of Southeastern WI | 12 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Cheryl Hillery, M.D.

**Education:** B.S. in Biochemistry, 1980
M.D., Medicine, 1984

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
University of Wisconsin-Madison, 1977-1978
Courses in Physics, 5 credit hours x 2

*Field:* *Radiation Protection*
University of North Carolina, 1989
Radiation Safety Training, 1 hour

The Blood Center of Southeastern WI, 1992-1994
Radiation Safety Training, 1 hour x 3

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Wisconsin-Madison, 1976-1978
Courses in Calculus, 5 credit hours x 4

*Field:* *Radiation Biology*
University of North Carolina, 1989
Radiation Safety Training, 1 hour

The Blood Center of Southeastern WI, 1992-1994
Radiation Safety Training, 1 hour x 3

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{51}Cr$ | 5 mCi | University of North Carolina | 1 year | Research |
| | 5 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{125}I$ | 5 mCi | University of North Carolina | 2 years | Research |
| $^{32}P$ | 20 mCi | University of North Carolina | 2 years | Research |
| | 2 mCi | Blood Center of Southeastern WI | 3 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Philip A. Kroner, Ph.D.

**Education:** B.S., Microbiology, Oregon State University, 1979
Ph.D., Botany, The University of Georgia, 1987

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
Physics, 2 quarters, Oregon State University, 1978

*Field:* *Radiation Protection*
Radiation Safety Training, The University of Georgia, 1979
Radiation Safety Training, University of Wisconsin-Madison, 1990
Radiation Safety Training, The Blood Center of Southeastern Wisconsin, 1990-1994

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
College Physics, 2 quarters, Oregon State University, 1978

*Field:* *Radiation Biology*
Physics, 2 quarters, Oregon State University, 1978
Radiation Safety Training, University of Wisconsin, 1990
Radiation Safety Training, The Blood Center of Southeastern Wisconsin, 1990-1994

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{3}H$ | 5 mCi | University of Georgia | 6 years | Research |
| | | University of Wisconsin-Madison | 4 years | Research |
| | | Blood Center of Southeastern WI | 5 years | Research |
| $^{35}S$ | 5 mCi | University of Georgia | 6 years | Research |
| | | University of Wisconsin-Madison | 4 years | Research |
| | | Blood Center of Southeastern WI | 5 years | Research |
| $^{14}C$ | 1 mCi | University of Georgia | 6 years | Research |
| $^{32}P$ | 2 mCi | University of Georgia | 6 years | Research |
| | | University of Wisconsin-Madison | 4 years | Research |
| | | Blood Center of Southeastern WI | 5 years | Research |
| $^{125}I$ | 2 mCi | Blood Center of Southeastern WI | 5 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Janice G. McFarland, M.D.

**Education:** Blood Banking, American Board of Pathology, 6/85
Hematology, American Board of Internal Medicine, 9/82
Internal Medicine, American Board of Internal Medicine, 9/80
Licensed to practice Medicine in Wisconsin

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4hrs/week x 6 weeks; Clinical rotation, 6 weeks

*Field:* *Radiation Protection*
University of Washington, Seattle, 1980-1983
Radiation Safety Course, 3hrs; Supervised Laboratory Experience, 2 years

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Oregon, Eugene, 1969-1973
Physics Course, 9hrs; Lab 4hrs

*Field:* *Radiation Biology*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4hrs/week x 6 weeks; Clinical rotation, 6 weeks

*Field:* *Radiopharmaceutical Chemistry*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4hrs/week x 6 weeks; Clinical rotation, 6 weeks

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 5 mCi | University of Washington, Seattle<br>Blood Center of Southeastern WI | 5 years | Research &<br>Clinical Testing |
| $^{51}Cr$ | 10 mCi | Blood Center of Southeastern WI | 4 years | Clinical Testing |
| $^{14}C$ | 1 mCi | Blood Center of Southeastern WI | 2 years | Clinical Testing |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Robert R. Montgomery, M.D.

**Education:** B.S. in Chemistry, June 1965
M.D., Pediatrics, June 1969
Licensed to practice Medicine in Wisconsin and Colorado

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
Scripps Clinic & Research Foundation
2hrs lecture/laboratory courses; 80hrs supervised lab experience

*Field:* *Radiation Protection*
Scripps Clinic & Research Foundation
2hrs lecture/laboratory courses; 80hrs supervised lab experience

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Scripps Clinic & Research Foundation
3hrs lecture/laboratory courses; 80hrs supervised lab experience

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 10 mCi | Scripps Clinic & Research Foundation | 1 year | Research |
| | 10 mCi | U. of CO School of Medicine | 3 years | Research |
| | 25 mCi | Medical College of Wisconsin | 10 years | Research |
| | 25 mCi | Blood Center of Southeastern WI | 10 years | Research |
| $^{131}I$ | 5 mCi | Blood Center of Southeastern WI | 10 years | Research |
| $^{14}C$ | 0.5 mCi | Blood Center of Southeastern WI | 10 years | Research |
| $^{35}S$ | 1 mCi | Blood Center of Southeastern WI | 10 years | Research |
| $^{32}P$ | 2 mCi | Blood Center of Southeastern WI | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: Peter J. Newman, Ph.D.

**Education:** B.S., Education/Biology, May 1976
M.S., Molecular Biology, May 1978
Ph.D., Pathology, May 1983

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Missouri-Columbia, 1972-1976
2 Physics courses with labs

*Field:* *Radiation Protection*
American Red Cross-Missouri/Illinois Region Research Labs
The Blood Center of Southeastern Wisconsin

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Missouri-Columbia, 1972-1976
Calculus courses, 3 hours x 2

*Field:* *Radiation Biology*
St. Louis University Medical School, 1980-1983
Pathology course, 5 hrs/week

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 5 mCi | Univ. of MO, St. Louis Univ., Blood Center of Southeastern WI | 11 years | Research |
| $^{35}S$ | 5 mCi | Univ. of MO, St. Louis Univ., Blood Center of Southeastern WI | 11 years | Research |
| $^{3}H$ | 25 mCi | Blood Center of Southeastern WI | 12 years | Research |
| $^{14}C$ | 5 mCi | Blood Center of Southeastern WI | 12 years | Research |
| $^{32}P$ | 2 mCi | Blood Center of Southeastern WI | 10 years | Research |
| $^{51}Cr$ | 5 mCi | Blood Center of Southeastern WI | 10 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Debra K. Newton-Nash, Ph.D.

**Education:** B.S., Psychology, 1981
Ph.D., Biology, 1989

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
Marquette University, Biology Dept., 1987
"Radioisotope Safety," 2 credit hours

*Field:* *Radiation Protection*
Marquette University, Biology Dept., 1987
"Radioisotope Safety," 2 credit hours

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Marquette University, Biology Dept., 1987
"Radioisotope Safety," 2 credit hours

*Field:* *Radiation Biology*
Marquette University, Biology Dept., 1987
"Radioisotope Safety," 2 credit hours

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{51}Cr$ | 5 mCi | Blood Center of Southeastern WI | 4 years | Research |
| $^{125}I$ | 3 mCi | Blood Center of Southeastern WI | 4 years | Research |
| $^{3}H$ | 5 mCi | Marquette Univ., Biology Dept. | 8 years | Research |
| | 5 mCi | Blood Center of Southeastern WI | 4 years | Research |
| $^{35}S$ | 5 mCi | Blood Center of Southeastern WI | 4 years | Research |
| $^{14}C$ | 1 mCi | Marquette Univ., Dental School | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER AND RSO

**Name**: Nancy J. Schunk

**Education:** B.S. in Chemistry, May 1982

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
Viterbo College, LaCrosse, WI, 1977-1980
IL State University, Normal, IL 1981-1982
Courses in Physics, Analytical Chemistry and Physical Chemistry, 3 hours x 6
Radiation Safety and Licensing Seminar, Stan A. Huber Consultants, Inc.,
Chicago, Illinois, May 3-4, 1990

*Field:* *Radiation Protection*
Medical College of Wisconsin, Milwaukee
Blood Center of Southeastern Wisconsin, On-the-Job Training
Radiation Safety and Licensing Seminar, Stan A. Huber Consultants, Inc.,
Chicago, Illinois, May 3-4, 1990

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Viterbo College, LaCrosse, WI, 1977-1980
Calculus courses, 3 hours x 3
Radiation Safety and Licensing Seminar, Stan A. Huber Consultants, Inc.,
Chicago, Illinois, May 3-4, 1990

*Field:* *Radiation Biology*
Medical College of Wisconsin, Milwaukee
The Blood Center of Southeastern Wisconsin, On-the-Job-Training
Radiation Safety and Licensing Seminar, Stan A. Huber Consultants, Inc.,
Chicago, Illinois, May 3-4, 1990

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{51}Cr$ | 10 mCi | Blood Center of Southeastern WI | 13 years | Res/Rad. Safety |
| $^{125}I$ | 10 mCi | Blood Center of Southeastern WI | 13 years | Res/Rad. Safety |
| $^{3}H$ | 500 mCi | Blood Center of Southeastern WI | 12 years | Res/Rad. Safety |
| $^{35}S$ | 10 mCi | Blood Center of Southeastern WI | 11 years | Radiation Safety |
| $^{14}C$ | 2 mCi | Blood Center of Southeastern WI | 9 years | Radiation Safety |
| $^{32}P$ | 10 mCi | Blood Center of Southeastern WI | 9 years | Radiation Safety |
| $^{59}Fe$ | 1 mCi | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{131}I$ | 5 mCi | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{111}In$ | 2 mCi | Blood Center of Southeastern WI | 2 years | Radiation Safety |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name**: John Paul Scott, M.D.

**Education:** B.S., Preprofessional Studies, June 1970
M.D., June 1974
Licensed to practice Medicine in Wisconsin and Illinois

**Training in Basic Radioisotope Handling Techniques**:

*Field:* *Radiation Physics & Instrumentation*
University of Colorado, Denver
Lecture/Lab courses, 2 hours; Supervised Laboratory Experience, 100 hours
Children's Memorial Hospital, Chicago, IL, Lecture/Lab courses, 2 hours

*Field:* *Radiation Protection*
University of Colorado, Denver
Lecture/Laboratory courses, 4 hours

Children's Memorial Hospital, Chicago, IL
Lecture/Laboratory courses, 4 hours

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Notre Dame - Physics
Lecture/Laboratory courses, 3 semester hours

*Field:* *Radiation Biology*
University of Colorado Medical Center, Denver
Lecture/Laboratory courses, 6 hours

*Field:* *Radiopharmaceutical Chemistry*
Loyola University, Stritch Medical School, Pathology
Lecture/Laboratory courses, 4 hours
University of Colorado, Denver, fellowship studies
Lecture/Lab courses, 4 hours; Supervised Laboratory Experience, 20 hours

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{14}C$ | 100 µCi | University of Colorado Medical Center | 1 year | Research |
| $^{125}I$ | 2 mCi | Children's Memorial Hospital | 6 months | Research |
| $^{35}S$ | 10 mCi | Blood Center of Southeastern WI | 1 year | Research |
| $^{3}H$ | 3 mCi | Blood Center of Southeastern WI | 1 year | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Peter J. Sims, M.D., Ph.D.

**Education:** B.A. in Biophysics, 1974
M.D., Medicine, 1980
Ph.D., Physiology & Pharmacology, 1980
Licensed to practice Medicine in Wisconsin

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
Duke University, School of Medicine, 4 hours x 4 years
University of Virginia, 1 hour x 5 years
Oklahoma Medical Research Foundation, 1 hour x 6 years

*Field:* *Radiation Protection*
Duke University, School of Medicine, 4 hours x 4 years
University of Virginia, 1 hour x 5 years
Oklahoma Medical Research Foundation, 1 hour x 6 years

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
Duke University, School of Medicine, 4 hours x 4 years
University of Virginia, 1 hour x 5 years
Oklahoma Medical Research Foundation, 1 hour x 6 years

*Field:* *Radiation Biology*
Duke University, School of Medicine, 4 hours x 4 years
University of Virginia, 1 hour x 5 years
Oklahoma Medical Research Foundation, 1 hour x 6 years

*Field:* *Radiopharmaceutical Chemistry*
Duke University, School of Medicine, 1 hour x 1 year

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$,$^{32}P$ | 10 mCi | Duke Univ./Univ. of Virginia | 15 years | Research |
| $^{3}H$,$^{14}C$ | 10 mCi | Duke Univ./Univ. of Virginia | 15 years | Research |
| $^{111}In$ | 10 mCi | Duke Univ./Univ. of Virginia | 3 years | Research |
| $^{42}K$ | 10 mCi | Duke Univ./Univ. of Virginia | 3 years | Research |
| $^{131}I$ | 5 mCi | Duke Univ./Univ. of Virginia | 15 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Gian Paolo Visentin, M.D.

**Education:** B.S. in Science, 1971
M.D. Medicine, 1980
Specialist in "General Pathology", University of Rome, Italy
Master in "Virology and Microbiology", University of Messina, Italy
Licensed to practice Medicine in E.E.C. Countries.

**Training in Basic Radioisotope handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
University of Naples, Italy, School of Medicine, 1974
Course of Radiochemistry, 2 hours x 24 weeks

*Field:* *Radiation Biology*
University of Naples, Italy, School of Medicine, 1975
Course in Radiation Biology, 2 hours x 23 weeks

*Field:* *Radiation Protection*
University of Naples, Italy, School of Medicine, 1976
Course in Radiation Safety, 1 hour x 25 weeks

*Field:* *Radiotherapy*
University of Rome, Italy, School of Medicine, 1987
Course in Radiotherapy, 1 hour x 10 weeks

*Field:* *Radiodiagnostic Techniques*
University of Rome, Italy, School of Medicine, 1988
Course in Radiodiagnostic Techniques, 1 hour x 10 weeks

**Experience with Radiation**:

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 8 mCi | S. Carlo Hospital, Potenza, Italy | 10 years | Clinical diagnosis |
| | 2 mCi | Blood Center of Southeastern WI | 5 years | Research |
| $^{131}I$ | 1 mCi | Blood Center of Southeastern WI | 1 year | Research |
| $^{3}H$ | 1 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{35}S$ | 2 mCi | Blood Center of Southeastern WI | 2 years | Research |

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Therese Wiedmer, Ph.D.

**Education:** B.S. in Biochemistry, 1973
Ph.D. in Membrane Biochemistry, 1977

**Training in Basic Radioisotope Handling Techniques:**

*Field:* *Radiation Physics & Instrumentation*
University of Bern, Switzerland, 1972
Course in Radiochemistry, 2 hours

*Field:* *Radiation Protection*
University of Virginia, 1980
Course in Radiation Safety, 10 hours

*Field:* *Mathematics in the Use/Measurement of Radioactivity*
University of Bern, Switzerland
Laboratory course in Radiochemistry, 40 hours/4 weeks

*Field:* *Radiation Biology*
University of Bern, Switzerland
Course in Radiation Biology, 40 hours/2 weeks

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 5 mCi | University of Virginia | 5 years | Research |
| | 5 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{3}H$ | 1 mCi | University of Bern, Switzerland | 4 years | Research |
| | 1 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{14}C$ | 1 mCi | University of Bern, Switzerland | 2 years | Research |
| | 1 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{32}P$ | 5 mCi | Duke University, Durham, N.C. | 2 years | Research |
| | 5 mCi | Blood Center of Southeastern WI | 3 years | Research |
| $^{45}Ca$ | 1 mCi | Oklahoma Medical Research Fdn | 7 years | Research |
| $^{42}K$ | 1 mCi | Oklahoma Medical Research Fdn | 7 years | Research |
| $^{86}Rb$ | 1 mCi | Oklahoma Medical Research Fdn | 7 years | Research |

## 9. FACILITIES AND EQUIPMENT.

Facilities

Radioactive materials are used in laboratories on the second and fifth floors of The Blood Center headquarters facility, 638 North 18th Street, and in the laboratory and lab support areas of The Blood Center Blood Research Institute, 8727 Watertown Plank Road. Radioactive waste is stored on the ground floor of headquarters. All areas where radioactive materials are used or stored are designated by diagonal lines on the floor plan drawings on pages 28 - 32.

Laboratories are equipped with standard radioactive handling tools such as forceps and tongs. Work is performed on surfaces lined with absorbent paper. Appropriately labeled waste containers are available in each lab.

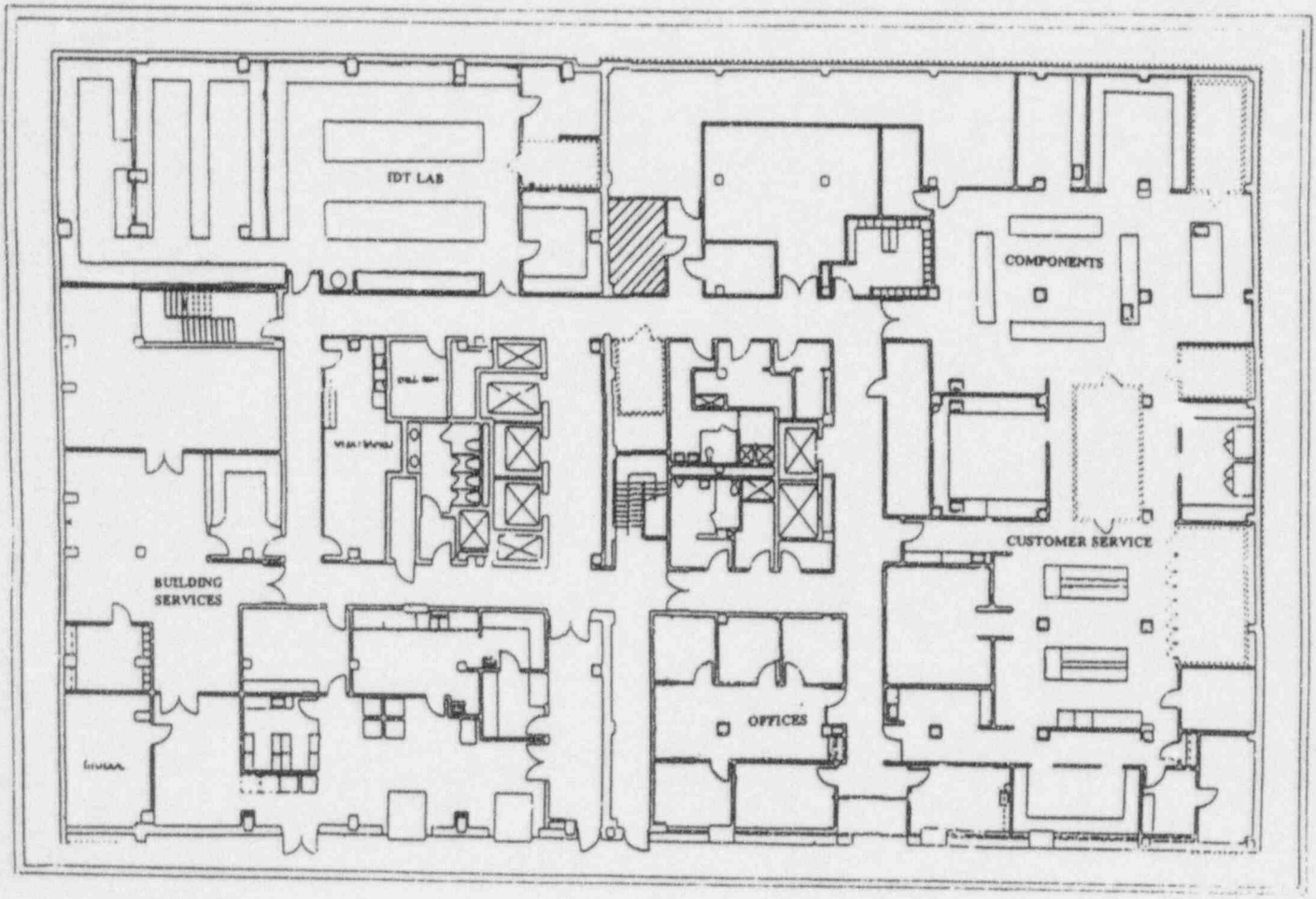
All iodine-125 or iodine-131 radiolabeling procedures performed at the Blood Research Institute are conducted in the radioiodination laboratory, which is dedicated exclusively to work with radioactive iodine. The fume hood exhaust duct is fitted with a cartridge-type filter unit utilizing a charcoal filter impregnated with triethylene diamine (TEDA). The molecular iodine removal efficiency of the filter is greater than 99.9%. An indicator has been installed to monitor air flow velocity, and is connected to a local alarm and building alarm system. The exhaust from this fume hood is a minimum of ninety-three feet from the nearest air intake.

Radioiodination procedures at headquarters are performed in a fume hood with a minimum face velocity of 100 feet per minute. A pneumatic indicator on the hood will alert users if the velocity falls below the minimum. Effluent monitoring is conducted on a regular basis at both facilities to ensure compliance with 10 CFR 20.1302.

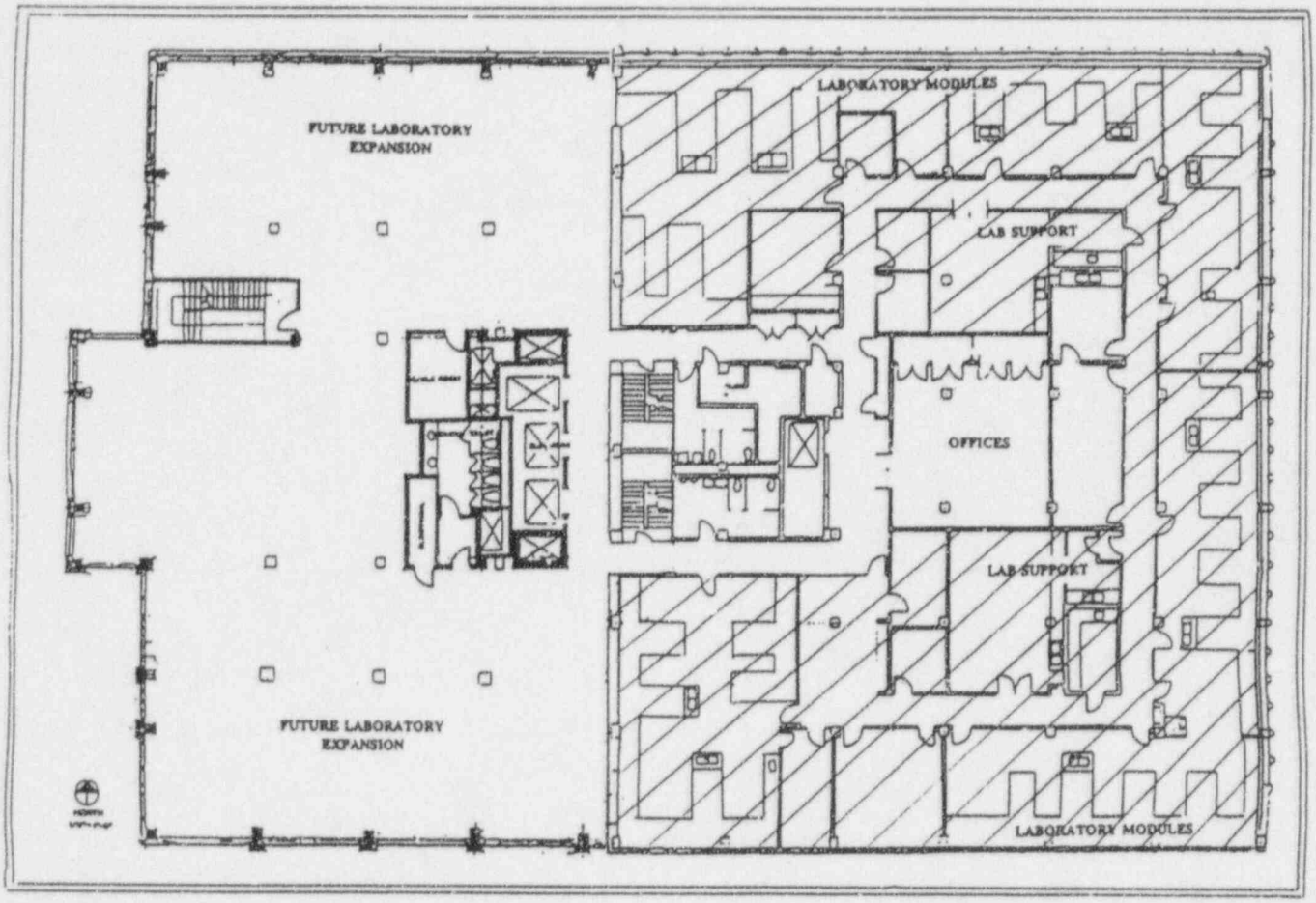
Both facilities have dedicated phosphorus-32 work areas, complete with shielding to limit exposure to the user and lab area. Shielding is composed of plexiglass of sufficient height and thickness to effectively shield the radioactivity.

All areas in both facilities where radioactive materials are used or stored are locked during non-working hours. Both facilities also have a security staff during non-working hours who inspect all areas of the facilities on a regular basis. Each facility also has space designated for decay-in-storage radioactive waste which are kept locked at all times.

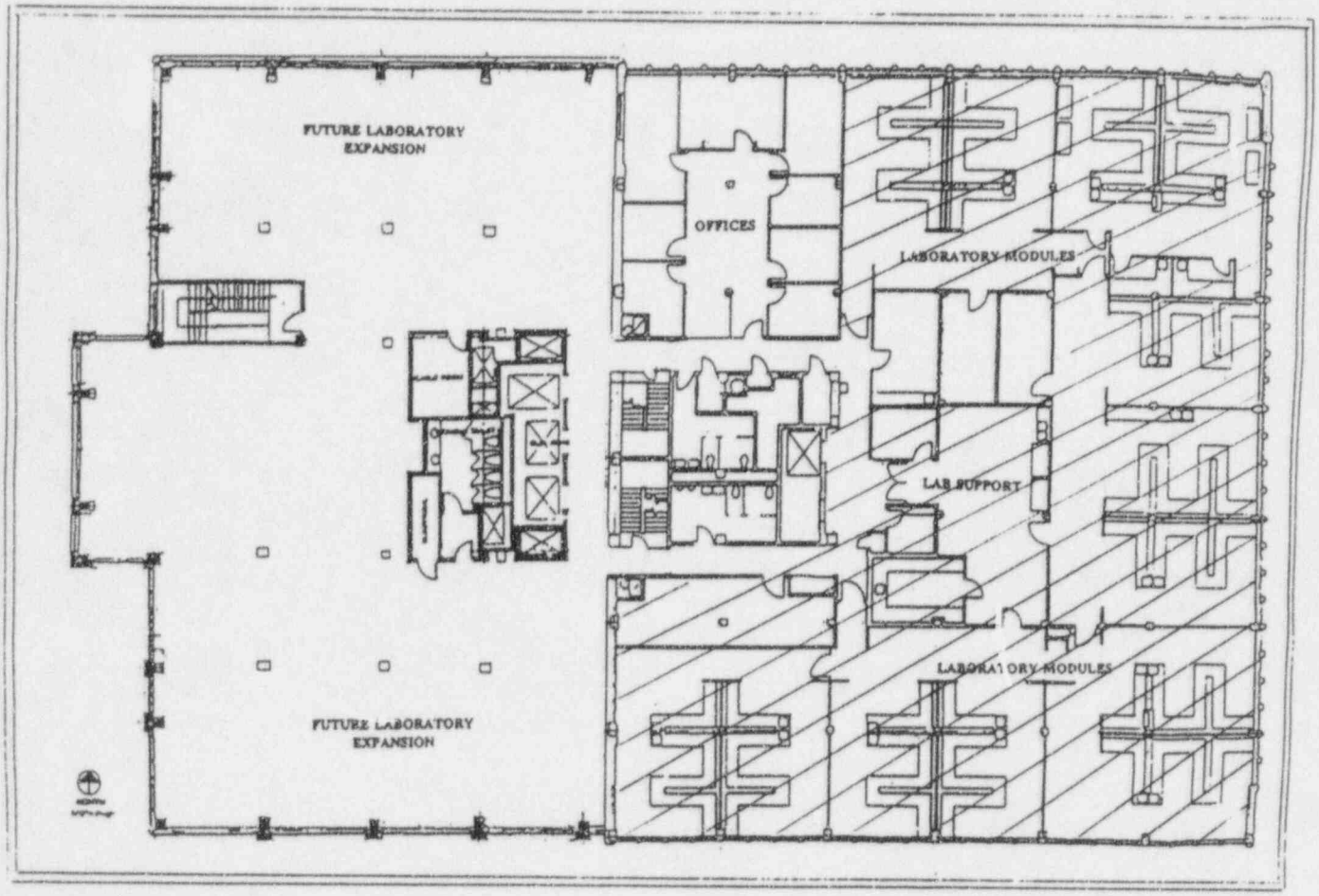
The Blood Center of Southeastern Wisconsin
Headquarters
638 North 18th Street
Ground Floor



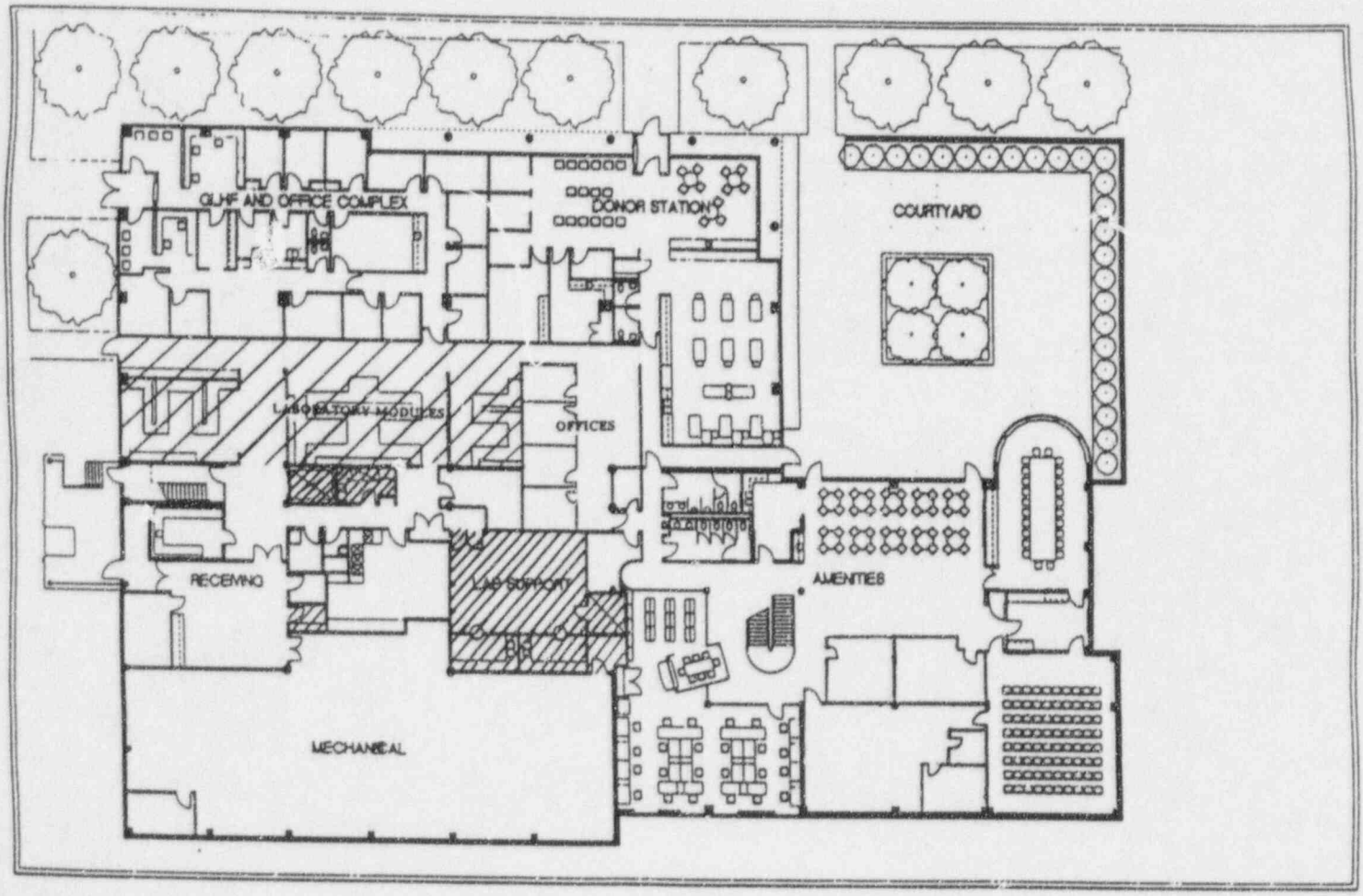
The Blood Center of Southeastern Wisconsin
Headquarters
638 North 18th Street
Second Floor



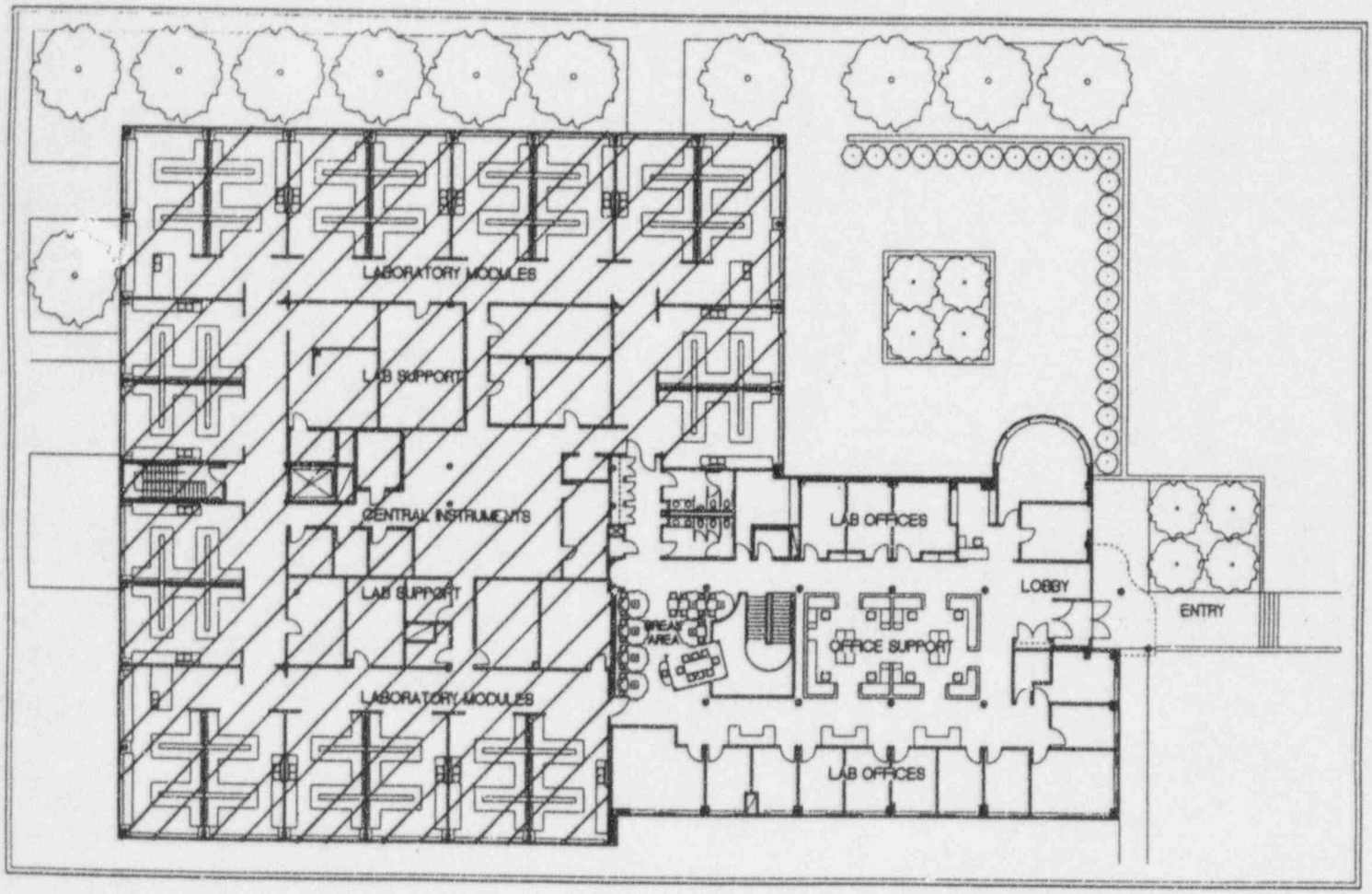
The Blood Center of Southeastern Wisconsin
Headquarters
638 North 18th Street
Fifth Floor



The Blood Center of Southeastern Wisconsin
Blood Research Institute
8737 Watertown Plank Road
First Floor



The Blood Center of Southeastern Wisconsin
Blood Research Institute
8737 Watertown Plank Road
Second Floor



## 9. FACILITIES AND EQUIPMENT.

Survey Meters

| Mfr | Model | Qty | Type of radiation detected | Sensitivity Range | Use |
|---|---|---|---|---|---|
| Ludlum[1] | 14C | 1 | alpha/beta/gamma | 0-2000 mR/hr | surveying |
| Ludlum[1] | 2 | 1 | alpha/beta/gamma | 0-200 mR/hr | surveying |
| Ludlum[1] | 3 | 6 | alpha/beta/gamma | 0-2000 mR/hr | surveying |
| Mini-Instruments | 900 | 1 | beta/gamma | 0-0.1 mR/hr | measuring |

[1]Ludlum survey meters use a pancake G-M detector (Ludlum Model 44-7 or 44-9) with window thickness 1.7 +/- 0.3 mg/cm$^2$ mica.

Scaler Ratemeters

| Mfr | Model | Qty | Type of radiation detected | Sensitivity Range | Use |
|---|---|---|---|---|---|
| Ludlum | 2200 | 2 | gamma | 0-500 cpm | monitoring |

Scaler Ratemeters are used with a I-125 specific gamma scintillator probe (Ludlum Model PR 44-3 or PR 44-17). Window thickness of each is 25 mg/cm$^2$ aluminum plus 8.2 mg/cm$^2$ mylar.

In accordance with 10 CFR 35.51 and 10 CFR 20.1501(b), all survey meters and scaler ratemeters will be calibrated before first use, annually, and following repair. Calibration will be performed by the company listed below or an equivalently licensed vendor.

Ludlum Measurements, Inc.
501 Oak Street
Sweetwater, TX 79556
License number LO-1963

## 9. FACILITIES AND EQUIPMENT.

Gamma Counters

| Mfr | Model | Qty | Type of radiation detected | Sensitivity Range | Window Thickness | Use |
|---|---|---|---|---|---|---|
| Abbott | 111 | 2 | gamma | N/A | N/A | measuring |
| Tracor | 1185 | 2 | gamma | N/A | N/A | measuring |
| Tracor | 1193 | 1 | gamma | N/A | N/A | monitoring |

Liquid Scintillation Counters

| Mfr | Model | Qty | Type of radiation detected | Sensitivity Range | Window Thickness | Use |
|---|---|---|---|---|---|---|
| LKB | 1218 Racbeta | 1 | beta | N/A | N/A | measuring |
| LKB | 1212 Racbeta | 1 | beta | N/A | N/A | measuring |
| LKB | 1410 | 1 | beta | N/A | N/A | monitoring |

All gamma and liquid scintillation counters used in quantitative analysis of wipe tests will be calibrated at least annually to ensure proper operation. Calibration will be performed by the companies listed below or an equivalently licensed vendor.

Source Seven
821 Albion Avenue
Schaumburg, IL 60193
License number IL-01539-01

Wallac Inc.
9238 Gaither Road
Gaitherburg, MD 20877
License number MD-31-071-01

## 10. RADIATION SAFETY PROGRAM.

General

The Blood Center operates its radiation safety program in accordance with the regulations contained in 10 CFR Parts 19 and 20. It has a written ALARA Program and procedures are in place for ordering radioactive materials, radioactive package receipt, check-in, and opening, wipe tests, radioiodinations, emergency or spill response, and disposal of radioactive materials.

Dosimeters

In accordance with 10 CFR 20.1502(a), all personnel who enter areas where radioactive materials are used and are likely to receive in one year a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a) wear appropriate dosimeters. In addition, finger TLD dosimeters are worn by all personnel handling more than 250 microcuries of high energy beta emitters (i.e., phosphorus-32), or more than 250 microcuries of penetrating gamma emitters. Film badges and TLD rings are exchanged monthly and processed by Siemens Medical Systems, Inc., or other processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP).

Bioassays

For monitoring personnel working with hydrogen-3, the procedures contained in "Guidelines for Bioassay Requirements for Tritium" are followed.

For monitoring personnel working with iodine-125 or iodine-131, the procedures contained in Regulatory Guide, "Applications of Bioassay for Iodine-125 and Iodine-131" are followed.

Air Monitoring

Air sampling is performed to assure that the release of radioactive iodine into the atmosphere does not exceed the concentrations specified in Appendix B, Table 2, Column 1 of 10 CFR 20. A sampling pump is used with filters constructed of triethylene diamine (TEDA) impregnated carbon which has a 99.95% minimum removal efficiency for elemental iodine.

If bioassays or planned activities indicate that personnel are likely to receive an intake in excess of 10 percent of applicable ALI in Appendix B, Table 1, Column 2 of 10 CFR Part 20, air sampling to determine the concentration of radioactive materials in air in work areas will be performed.

## 10. RADIATION SAFETY PROGRAM.

Wipe Tests

All areas where radioactive materials are used or stored are wipe tested weekly or after experiment involving radioisotopes and the results recorded in a laboratory wipe test book. If removable contamination exceeds 200 dpm/100 $cm^2$, the area is decontaminated and retested. If no radioactive material was used during that week, a notation stating such is made in the wipe test book. The only areas excepted from this policy are the controlled areas where radioactive waste is stored for decay in storage.

Surveys

At a minimum, exposure rate measurements (surveys) of all areas where radioactive materials are used or stored are performed and recorded quarterly. More frequent monitoring of some areas, especially areas in which phosphorus-32 is used, may be required by the Radiation Safety Officer.

Records

As required in 10 CFR Parts 19, 20 and 35, all necessary documentation will be maintained.

## 11. WASTE MANAGEMENT.

General Provisions

Licensed material is only disposed of by authorized means. Waste volume will be minimized through segregation and compaction. Compaction will include only those items, such as gloves or paper, contaminated with non-volatile radioisotopes.

In accordance with 10 CFR 20.1904(b) all radioactive material labels and markings on empty uncontaminated containers are removed or defaced prior to disposal to unrestricted areas so as to clearly indicate that the container no longer contains radioactive materials.

Specific Waste Programs

1. Decay in Storage. Byproduct material with a physical half-life of less than 90 days is held for decay in storage for a minimum of 10 half-lives before disposal in ordinary trash. All radioactive material labels and markings are removed or defaced from waste destined for decay-in-storage to ensure that the markings are not present when the waste is released for disposal in unrestricted areas. Before disposal in ordinary trash, decay-in-storage waste is surveyed to determine that its radioactivity cannot be distinguished from background.

2. Disposal by Release into Sanitary Sewer Systems. Licensed material is discharged into a sanitary sewer system in accordance with the provisions of 10 CFR 20.2003. Calculations to determine monthly concentrations and quantities of radioactive material disposed of in this manner will be performed at least annually.

3. Disposal of Specific Wastes. As specified in 10 CFR 20.2005 limited quantities of hydrogen-3 and carbon-14 may be disposed of without regard to radioactivity. Compliance will be maintained with all other applicable regulations and regulatory agencies.

4. Storage. Until other options are available, radioactive waste contaminated with hydrogen-3 and carbon-14 is being stored indefinitely. The possession limits for these isotopes will be maintained.

5. Transfer for Disposal. The requirements of 10 CFR 20.2006 are followed when radioactive waste is transferred to ADCO Services, or another waste broker licensed by the NRC or an agreement state, for treatment, incineration, decay in storage, or disposal.

# Radiation Safety Rules
# The Blood Center of Southeastern Wisconsin

1. **Utilize Appropriate Protective Measures**

   Always wear gloves and a lab coat when working with any radioactive materials. Use shielding and/or remote handling tools as indicated by the specific procedure you are performing. All radioiodinations are performed in the radioiodination fume hoods located in the central equipment room on the fifth floor downtown and on the ground floor at the Blood Research Institute.

2. **No Eating, Smoking or Drinking in the Lab**

   Never store food or beverages in lab areas. Do not apply cosmetics in the lab. No gum chewing while working with radioactive materials.

3. **Confine Radioactive Materials to Restricted Areas**

   The areas in The Blood Center where radioactive materials are used or stored are referred to as controlled areas and include all laboratory areas at the Blood Research Institute and the following downtown labs: Cellular Typing, DNA Paternity, Hemostasis, Platelet Antibody, and Transfusion Medicine. All radioactive material must be confined to these areas. When transporting radioactive samples or reagents between these areas, samples should be placed in a secondary, leakproof container. Do not stop in the employee lounges, office areas, or other non-laboratory areas while transporting radioactive materials.

4. **Wear Your Badge**

   Film badges are issued to all employees working with radioactive materials. TLD rings are issued to those people working with $^{32}P$ and millicurie quantities of $^{125}I$ and $^{51}Cr$. You are expected to wear these monitoring devices. They are exchanged on the 10th of each month and sent to Siemens for evaluation. Individuals are notified in writing of any radiation dose received. If you do not receive written notification, you may assume that you received no exposure.

5. **Monitor and Decontaminate**

   It is your responsibility to monitor all areas and equipment used when working with radioactive materials and to clean up any removable contamination you find. Each lab has established specific wipe test procedures and contains a wipe test book in which all monitoring activity is to be recorded.

6. **Use Proper Labeling**

This requirement is especially important for safety of others working with you and around you. All radioactive materials must be properly labeled before storage. To be properly labeled, the container must have the following information on it: the universal radioactive symbol, your name, the isotope, and the date. If the radioactive material is being stored in a small tube or vial, place the vial in a secondary container with the proper information on it. A radioactive experiment left running over night should be labeled as such. Equipment and glassware that are used solely for radioactive experiments should be labeled with the radioactive symbol. Never send these items to housekeeping for cleaning or to maintenance for repair.

7. **Maintain Accurate Records**

The records that you are responsible for maintaining are: the radioactive aqueous waste log, the record of radioactive materials use log, the wipe test book in your lab, the wipe test log on the radioiodination hood, and any equipment logbook that requests information about radioactive material use.

8. **Report All Incidents/Spills**

Anytime there is personnel contamination the Radiation Safety Officer, the Supervisor of Occupational Health and Safety, or the Safety Coordinator should be notified immediately. Specific information is contained on the attached emergency procedures handout.

9. **Dispose of Radioactive Waste Correctly**

All radioactive waste with a half-life of 60 days or less is stored for decay for a minimum of ten half-lives, monitored to assure that detectable radiation levels are less than background, and disposed of in the regular trash. Other waste is being transferred to a commercial broker for disposal. We currently do not have a method to dispose of the radioactive waste from $^{3}H$ and $^{14}C$ and are storing this waste until the State of Wisconsin develops its plan for disposal of low-level radioactive waste. It is critical that radioactive waste is properly segregated. All radioactive symbols must removed or obliterated. Paper and plastic contaminated with radioactive materials must be segregated from liquids. Any potentially volatile $^{125}I$ must be sealed and placed in the barrel designated for $^{125}I$ waste. The disposal receptacles are clearly marked; if you have any questions regarding the proper way in which to dispose of your radioactive trash, ask before you toss.

**Radiation Safety Emergency Procedures**
**The Blood Center of Southeastern Wisconsin**

## Minor Spills Involving no Radiation Hazard to Personnel

1. Notify other people in the area to avoid accidental spread of material.
2. Confine the spill immediately by dropping absorbent paper on the spill.
3. Decontaminate the area using good radiation safety practices and procedures.
4. Wipe test area.
5. Repeat decontamination and wipe test, as necessary.
6. Dispose of contaminated waste properly.
7. Describe spill and record wipe test results in laboratory wipe test book.

## Major Spills

1. Instruct all people not involved in spill to leave the area.
2. Confine the spill immediately by dropping absorbent paper on the spill.
3. Notify the Radiation Safety Officer, Safety Supervisor, or Safety Coordinator.
4. Decontaminate area under the supervision of Radiation Safety staff.
5. Wipe test area.
6. Repeat decontamination and wipe test, as necessary.
7. Dispose of contaminated waste properly.
8. Monitor all personnel in vicinity of the spill as indicated by the extent and hazard of the spill.
9. Complete a *Form Q* to document the incident for the Radiation Safety files.

## All Spills on Skin or Clothing

1. Remove outer garments immediately if spill is on clothing.
2. If spill is on skin, flush immediately with water.
3. Notify the Radiation Safety Officer, Safety Supervisor, or Safety Coordinator.
4. Do not damage skin while decontaminating.
5. Monitor skin and record results.
6. Complete a *Form Q* to document the incident for the Radiation Safety files.

NOV 0 6 1996

Nancy A. Drzewiecki
Supervisor, Occupational Health and Safety
Blood Center of Southeastern Wisconsin
P.O. Box 2178
Milwaukee, WI 53201-2178

Dear Ms. Drzewiecki:

Enclosed is Amendment No. 25 renewing your NRC Material License No. 48-02000-01 in accordance with your request.

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

Please note as discussed with Nancy Schunk on November 1, 1996, we have not authorized Dr. Janice G. McFarland to use chromium-51 at this time because we need a completed preceptor statement (see enclosed Supplements A and B), to complete our review. If you wish to pursue this matter, please resubmit your request as additional information to Control 398510.

Please be advised that we cannot authorize you to release your old storage area located at 1725 West Wisconsin Avenue, Milwaukee, Wisconsin until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

a. A history of all radionuclides used at your old storage area.

b. A current copy of the leak test results for the sealed sources stored in your old storage area. Also a history of leaking sealed sources (if any).

c. A diagram of your old facility with survey and wipe test results keyed to specific locations. Please record your survey results using the appropriate units as described in 10 CFR 30.36(j)(2)(i)(copy enclosed).

d. The name of the person performing the survey.

e. The date the survey was performed.

398510

f. The instrument(s) used for exposure rate measurements and for analysis of the wipes.

g. Background readings.

h. The date that the survey instrument was last calibrated.

Please submit your close-out survey as additional information to Control 398510.

Also note, we have removed the license condition requiring decommissioning records because this requirement is in the regulations.

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

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

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

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

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

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

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

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

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

   d. Change ownership of your organization.

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

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

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

Sincerely,

Original Signed By
W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 48-02000-01
Docket No.: 030-03424

Enclosures:
1. Amendment No. 25
2. Part 30.36(j)
3. Decontamination Guide
4. Supplements A & B, Preceptor & Training & Experience
5. New License Package

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OFFICIAL RECORD COPY

The Blood Center
of Southeastern Wisconsin

October 4, 1996

Bill Reichhold
Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Mail Control Number 931109

Dear Mr. Reichhold:

This letter is in response to your facsimile of September 23, 1996, requesting additional information regarding the renewal of our NRC Byproduct Material License Number 48-02000-01. Each of your concerns is specifically addressed below.

**Opening Package Procedures**

1. Normal Trash Disposal of Emptied Packages

Geiger Mueller counter surveys will be performed to detect any radiation from empty packaging material before the material is disposed of as normal trash.

2. Damaged Packages

If there is evidence of degradation of package integrity when a package containing radioactive materials is received at The Blood Center (e.g., the package is crushed, wet, or damaged), the Radiation Safety Officer or a member of the Radiation Safety staff is immediately contacted. Wipe tests and Geiger Mueller counter surveys are performed to determine radiation levels and to check for radioactive contamination.

**Survey Procedures**

1. Radioiodinations

Geiger Mueller counter surveys and wipe tests will be performed after each iodination procedure to detect any contamination.



638 North 18th Street
P.O. Box 2178
Milwaukee, WI 53201-2178
(414) 933-5000
FAX (414) 937-6332

2. Ambient Radiation Level Surveys

At a minimum, ambient radiation level surveys will be performed and recorded monthly in all areas where radioactive materials are used, excluding those areas where only tritium is used since its low energy cannot be detected with Geiger Mueller counters.

All areas where radioactive materials are used or stored are wipe tested weekly or after each experiment involving radioisotopes and the results recorded in a laboratory wipe test book. If removable contamination exceeds 200 dpm/100 $cm^2$, the area is decontaminated and retested. If no radioactive material was used during that week, a notation stating such is made in the wipe test book. The only areas excepted from this policy are controlled areas where radioactive waste is stored for decay in storage.

**Authorized User for *In Vivo* Studies**

Janice G. McFarland, M.D., has been an Authorized User at The Blood Center for 6 years and has had over 40 hours of classroom and laboratory training in basic radioisotope handling techniques as well as over 20 hours of supervised clinical experience, including six weeks of training in radiation oncology. Her clinical experience has been under the supervision of an Authorized User and has included:

Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contradictions;

Selecting the suitable radiopharmaceuticals and calculating and measuring the doses;

Administering dosages to patients or human research subjects and using syringe radiation shields;

Collaborating with the Authorized User in the interpretation of radioisotope test results; and

Patient follow-up.

Please contact me at (414) 937-6380 if you have any questions or if additional information is required.

Sincerely,

Nancy A. Drzewiecki

Nancy A. Drzewiecki
Supervisor, Occupational Health and Safety

# TRANSMIT CONFIRMATION REPORT

| | | |
|---|---|---|
| NO. | : | 004 |
| RECEIVER | : | 414 937 6332 |
| TRANSMITTER | : | US NRC REGION III |
| DATE | : | SEP 23'96 9:31 |
| DURATION | : | 02'31 |
| MODE | : | STD |
| PAGES | : | 04 |
| RESULT | : | OK |

OPTIONAL FORM 99 (7-90)

**FAX TRANSMITTAL** # of pages ▶ 4

| | |
|---|---|
| To: Nancy Drzewiecki | From: Bill Reichhold |
| Dept./Agency: Blood Ctr. of Southeast Wi. | Phone #: (630) 829-9839 |
| Fax #: (414) 937-6332 | Fax #: (630) 515-1259 |

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

# UNITED STATES NUCLEAR REGULATORY COMMISSION

**REGION 3**
**801 WARRENVILLE ROAD**
**LISLE, ILLINOIS 60532-4351**

PHONE CONVERSATION RECORD

20 September 1996
Nancy Drzewiecki
Blood Center of Southeastern Wisconsin
Milwaukee, Wisconsin

Dear Ms. Drzewiecki,

The following additional information is needed to complete the review of your renewal application.

**Opening Package Procedures**

1. Please clarify if your procedure includes performing a G-M survey to detect any radiation from empty packaging material before the material is disposed of as normal trash.

2. Please clarify if you will monitor all packages known to contain radioactive material for radioactive contamination (wipe test) and radiation levels (G-M survey) if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged (see 10CFR 20.1906(b),(3) ).

**Survey Procedures**

1. Please clarify if you will perform G-M surveys after each iodination to detect any radioactive contamination. If you only perform a wipe test after iodinations, there is a good chance that you may not identify spots or areas that are contaminated.

2. Please clarify if you will perform monthly G-M surveys and wipe tests monthly in areas where radioactive material is used. Normally, monthly G-M survey and wipe tests are performed in laboratory areas were only small quantities of radioactive material (less than 200 microcuries at any one time) are used(see enclosed).

**Authorized User**

Please clarify if Dr. Janice McFarland's clinical experience includes the items listed in 10 CFR 35.910 (b) (2)(see enclosed).

Please respond to the above within 15 days and refer to **mail control 931109.** Please call me at 630-829-9839 if you have any questions.

Sincerely,

Bill Reichhold

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(1) 40 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61786, Dec. 2, 1994]

### §35.920 Training for imaging and localization studies.

Except as provided in §35.970 or 35.971, the licensee shall require the au-

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and

(b) Each licensee shall—

(1) Monitor the external surfaces of a labeled [3a] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

(2) Monitor the external surfaces of a labeled [3a] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in § 71.4 and appendix A to part 71 of this chapter; and

57 FR 39353

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(c) The licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20 when—

60 FR 20183

(1) Removable radioactive surface contamination exceeds the limits of § 71.87(i) of this chapter; or

(2) External radiation levels exceed the limits of § 71.47 of this chapter.

(e) Each licensee shall—

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

56 FR 23360

(f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of paragraph (b) of this section, but are not exempt from the survey requirement in paragraph (b) of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

**Table 1**

## SURVEY FREQUENCIES

1. All elution, preparation, and injection areas should be surveyed daily with a survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material (less than 200 μCi at any one time) are used should be surveyed monthly.

3. All other laboratory areas should be surveyed weekly.

4. The weekly and monthly surveys should consist of the following:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/h.

   b. A series of smear tests to measure contamination levels. The method for performing smear tests should be sufficiently sensitive to detect the limits in Table 2 to one significant digit.

   c. Any air sample measurements necessary to determine compliance with §20.103 of 10 CFR Part 20 in cases where calculations alone are not sufficient.

The Blood Center
of Southeastern Wisconsin

September 5, 1996

Bill Reichhold
Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Mail Control Number 398510

Dear Mr. Reichhold:

This letter is in response to your letter of August 19, 1996, requesting additional information regarding the renewal of our NRC Byproduct Material License Number 48-02000-01. Each of your questions is specifically addressed below.

1. Maximum Amount of Activity Used in *In Vitro*, Labeling, and Clinical Studies

The maximum amount of activity currently used in our *in vitro* studies for biomedical research and clinical diagnostics is 0.5 millicuries, with typical usage amounts ranging from 0.001 millicuries to 0.050 millicuries.

The maximum amount of activity currently used for radiolabeling for *in vitro* use is 10.0 millicuries, with typical usage amounts ranging from 0.005 millicuries to 5.0 millicuries.

The maximum amount of activity currently used in our *in vivo* studies for biomedical research is 0.040 millicuries, with typical usage amounts ranging from 0.010 to 0.030 millicuries.

2. Radionuclides Used by the Following Individuals

Outlined below are the radionuclides the following individuals wish to use:

| | |
|---|---|
| Daniel B. Bellissimo, Ph.D. | All, except 35.100 material |
| Nancy A. Drzewiecki | All, except 35.100 material |
| Gian P. Visentin, M.D. | All, except 35.100 material |



638 North 18th Street
P.O. Box 2178
Milwaukee, WI 53201-2178
(414) 933-5000
FAX (414) 937-6332

3. Termination of Individuals as Authorized Users

The following individuals may be deleted as Authorized Users from our license:

Lee Ann Baxter-Lowe, Ph.D.

Paul A. Foster, M.D.

Amy Goldberger, Ph.D.

Brian P. Lawton

4. Calibration of Survey Meters and Well Counters

All survey meters and scaler ratemeters will be calibrated before first use, at a mimimum of every twelve months, and following repair. All gamma and liquid scintillation counters used in quantitative analysis of wipe tests will be calibrated at a minimum of every twelve months to ensure proper operation.

5. Fume Hood Alarm

The fume hood at headquarters used for radioiodinations has a pneumatic indicator to alert users if the velocity of the air flow falls below the minimum.

The fume hood in the radioiodination laboratory at the Blood Research Institute has an indicator used to monitor air flow velocity. This indicator is connected to a local alarm and building alarm system. If air flow drops below an acceptable level for use, the alarm sounds.

6. Ambient Radiation Level Surveys

At a minimum, ambient radiation level surveys will be performed and recorded monthly in all radioactive waste storage areas and quarterly in all areas where radioactive materials are used or stored. We do not believe that performing ambient radiation level surveys monthly in all areas will provide any safety benefits or increase ALARA. The amount of radionuclides used in any one area is very small and the ambient radiation level surveying already performed quarterly has never shown any radiation levels above background.

Wipe-tests for contamination are performed after each radioiodination procedure. Ambient radiation level surveys are not performed since all equipment and surfaces are cleaned and wipe-tested after each use. Attachment A is a copy of the standard operating procedure in place regarding radiation safety for radioiodination procedures.

7. Labeling of Radioactive Waste in the Decay in Storage Area

All radioactive decay in storage waste is placed into locked storage rooms that are solely used for the storage of radioactive waste. Access to these rooms is only available upon approval of the Radiation Safety Officer or a designated member of the radiation safety staff. The storage rooms are labeled on the outside with the radiation symbol and the words "Radioactive Materials".

The radioactive waste containers are labeled on the outside with the radionuclides held within, the date sealed, and the date indicating the end of ten half lives. All radioactive material labels and markings are removed or defaced from waste destined for decay in storage to ensure that the markings are not present when the waste is released for disposal in unrestricted areas.

8. Standard Operating Procedures

Attachment B is a copy of our standard operating procedure for ordering packages containing radioactive materials. Attachments C, D, and E are copies of our standard operating procedures for receiving and opening packages containing radioactive materials. These procedures are reviewed and maintained by the Radiation Safety Officer with the assistance of the Occupational Health and Safety Department.

9. Decay-in-Storage of Radioactive Materials with Half-lives Greater than 65 Days

At this time, we are able to ship our radioactive materials with half-lives greater than 65 days to a licensed facility for decay in storage. We therefore withdraw our request to increase our decay in storage program to include holding radioactive material with half-lives greater than 65 days.

10. Primary Use of Radionuclides

The primary use of radionuclides in our program is *in vitro* studies for biomedical research and clinical diagnostic testing. Our laboratories perform basic research and development as defined in 10 CFR part 30.4, in a wide variety of areas including transfusion medicine, blood diseases, immunohematology, vascular biology, and transplantation. Radionuclides are also used to perform *in vitro* diagnostic testing in such areas as hemostasis, platelet antibody, and paternity testing.

Uses of radiolabeled proteins and antibodies include *in vitro* research on platelet aggregation and secretion, sickle cell disease, and blood clotting factors. Radiolabeled DNA and RNA are used to perform genetic and protein sequencing for both research and clinical tests. *In vitro* studies on the metabolism of leukocytes and endothelial cells are also performed using radionuclides.

*In vivo* use is limited to a very small number of biomedical research studies on red blood cell and platelet survival.

11. Audit Program

Every laboratory at each location that uses or stores radioactive material is audited quarterly by the Radiation Safety Officer or a designated member of the Occupational Health and Safety Department. This audit includes a review of all wipe-test data and records regarding usage and disposal of radioactive materials as well as the performance of ambient radiation level surveys. Attachment F is an example of the Quarterly Radiation Safety Audit form completed for each laboratory.

All records regarding the use of radioactive materials are centralized in the Occupational Health and Safety Department and are also audited quarterly. The audit includes a review of all occupational exposure data, disposal records, radiation safety training performed, and incidents reported. Attachment G is an example of the RSO Report that is compiled quarterly.

The results of these audits and any corrective action taken are reported to the Radiation Safety Committee at its quarterly meetings.

Biweekly safety meetings between the Radiation Safety Officer, the Occupational Health and Safety Department, and the Supervisors of Research Laboratory Operations are held so that problems that occur between audits can be immediately addressed.

New employee and annual radiation safety training for employees at both locations is performed by the Occupational Health and Safety Department under the direction of the Radiation Safety Officer and a member of the Occupational Health and Safety Department typically visits each location weekly.

Additional Information

Additional information is provided below regarding our license renewal to reflect changes that have occurred since our license renewal was filed.

1. Change in Radiation Safety Officer

We are requesting Nancy A. Drzewiecki be designated the Radiation Safety Officer for The Blood Center. Ms. Drzewiecki has worked at The Blood Center for over two years and is the Supervisor of the Occupational Health and Safety Department. In this position, Ms. Drzewiecki's responsibilities have included preparing and conducting radiation safety training programs, incident investigation, performing bioassays such as thyroid scans and urinalysis, waste disposal, and the development of written policies and procedures. Her research experience includes performing radiolabeling, radioiodinations, and cell studies. Ms Drzewiecki's training and experience is detailed in Attachment H.

Nancy J. Schunk, the current Radiation Safety Officer, will remain an Authorized User and become the Assistant Radiation Safety Officer. Ms. Schunk has been The Blood Center's Radiation Safety Officer for the past 9 years.

2. Additional Radiation Safety Staff

The Radiation Safety Officer and Assistant Radiation Safety Officer are assisted in the daily operations of the radiation safety program by Mary L. Pawlak and Nancy Szatkowski, Ph.D., Supervisors of Research Lab Operations, and Laura E. Schloesser, Safety Coordinator.

3. Possession of Indium-111

Since accelerator-produced radioisotopes are not licensed by the Nuclear Regulatory Commission, we withdraw our request to be licensed by the Nuclear Regulatory Commission to possess Indium-111. We are already registered with the Department of Health and Family Services in the State of Wisconsin to possess this radioisotope.

4. Expansion of Laboratory Space

Radioactive materials are used in laboratories on the second and fifth floors of The Blood Center headquarters facility, 638 North 18th Street, and in the laboratory and lab support areas of The Blood Center Blood Research Institute, 8727 Watertown Plank Road. Radioactive waste is stored on the ground floor of headquarters.

Our laboratory areas for the fifth floor of our headquarters facility at 638 North 18th Street have expanded. All areas where radioactive materials will be used or stored on the fifth floor are designated by diagonal lines on the floor plan drawing on Attachment I.

5. Changes in Radiation Detection Instruments

Outlined below is a current list of survey meters in use at The Blood Center:

| Mfr | Model | Qty | Type of Radiation Detected | Sensitivity Range | Use |
|---|---|---|---|---|---|
| Ludlum[1] | 14C | 1 | alpha/beta/gamma | 0-2000 mR/hr | surveying |
| Ludlum[1] | 2 | 1 | alpha/beta/gamma | 0-200 mR/hr | surveying |
| Ludlum[1] | 3 | 7 | alpha/beta/gamma | 0-2000 mR/hr | surveying |
| RPI[2] | GM1 | 1 | beta/gamma | 0-80 mR/hr | surveying |

[1]Ludlum survey meters use a pancake G-M detector (Ludlum Model 44-7 or 44-9) with window thickness 1.7 +/- 0.3 mg/cm$^2$ mica.

[2]The RPI survey meter uses an end window G-M detector with window thickness 1.7 +/- 0.3 mg/cm$^2$ mica.

6. Addition of an Authorized User for Medical Use Described in 10 CFR 35.100

We are requesting authorization to allow Janice G. McFarland, M.D., to perform *in vivo* studies as described in 10 CFR 35.100. Dr. McFarland has been an Authorized User at The Blood

Center for 6 years and has worked at The Blood Center for over 12 years with Richard H. Aster, M.D., who is currently licensed to use materials specified in 10 CFR 35.100 and who has been authorized for this use in NRC license number 48-0200-01 since June 12, 1970.

Dr. McFarland has had over 40 hours of classroom and laboratory training in basic radioisotope handling techniques as well as over 20 hours of supervised clinical experience, including six weeks of training in radiation oncology. Her training and experience is detailed in Attachment J.

Please contact Nancy Drzewiecki at (414) 937-6380 if you have any questions or if additional information is required.

Sincerely,

Nancy A. Drzewiecki
Supervisor, Occupational Health and Safety

Nancy J. Schunk
Manager, Quality Assurance and Safety

| TITLE: Radiation Safety for Radioiodination Procedures - Headquarters | | |
|---|---|---|
| DEPARTMENT: Occupational Health and Safety | QA Approved 3/28/96 NS | SOP 10-3420 |
| EFFECTIVE DATE: March 31, 1996 | REV: | Page 1 of 4 |

## 1.0 PURPOSE/PRINCIPLE

To provide a safe working environment when using volatile radioactive iodine and thereby to minimize employee exposure to the radioactive iodine.

Special safety precautions above and beyond those used with all radioactive materials are necessary when working with volatile radioactive iodine due to the potential for the radioactive iodine to be taken in and concentrated in the thyroid, resulting in long term health effects that can include hypothyroidism and thyroid cancer.

## 2.0 SPECIAL NOTES

2.1 Radioiodination procedures are performed only in the hood designated for such use and approved by the Radiation Safety Officer.

2.2 Gloves, lab coats, radiation detection badges, and thermoluminescent dosimeter (TLD) rings must be worn when performing radioiodinations. TLD rings are to be worn under the gloves with the face of the ring towards the palm.

2.3 Sodium iodide can penetrate latex and vinyl gloves fairly rapidly and so additional care must be taken to prevent exposure to the hands; therefore, double-gloving and frequent Geiger-Mueller counter monitoring of the hands are necessary.

2.4 Keep the hood sash down as far as possible. The hood sash must remain lower than the red arrow mark labeled "Do not raise sash above this mark." Above this mark, the face velocity of the hood drops below the minimum velocity of 100 linear feet per minute required for radioiodinations.

2.5 Vials containing radioiodine should be opened and used only in the designated hood for as brief a time as necessary and covered tightly when not in use.

2.6 Do not add acids to radioactive iodine solutions as the volatility of radioiodine is enhanced significantly at low pH.

2.7 A thyroid scan will be performed by the Occupational Health and Safety Department on every individual involved in the radioiodination between 6 hours to 10 days after the radioiodination occurred. If the thyroid scan indicates an uptake by the thyroid of 12 nCi or greater, the Radiation Safety Officer will be immediately notified.

## 3.0 MATERIALS REQUIRED

Disposable absorbent paper
Small plastic bags
Parafilm
Aluminum foil
Tape
Rad-Con surface cleaner
Premoistened alcohol swabs
Counting vials

## 4.0 EQUIPMENT REQUIRED

Geiger-Mueller counter
Gamma counting instrument

QA Approved 5/29/96 AS

## 5.0 RECORDS

Printout of wipe test data
Hood Wipe Tests form

The wipe test data and the Hood Wipe Tests form will be reviewed by the Radiation Safety Officer or designee and kept for a period of not less than three years following the date of the wipe-test.

## 6.0 PROCEDURE

6.1 Turn the hood on.

6.2 Check the vent hood fan pneumatic indicator found on the upper left face of the hood to ensure that the face velocity of the hood is at least 100 linear feet per minute.

6.2.1 If the indicator is black, the minimum velocity is at least 100 linear feet per minute and the hood can be used.

6.2.2 If the indicator is red, the face velocity of the hood is below 100 linear feet per minute. Contact the Occupational Health and Safety Department and do not proceed with the radioiodination.

6.3 Lower the hood sash below the red arrow mark labelled "Do not raise sash above this mark." Keep the hood sash as low as possible.

6.4 Line the work area of the hood (sides and bottom) with disposable absorbent paper.

6.5 Place a small plastic bag and several conical tubes with caps in the hood for disposal of contaminated items.

6.6 Assemble everything (i.e., equipment, solutions, instruments) required for the radioiodination before using the radioactive iodine.

6.7 If there is likely to be volatile species in the vial containing the radioactive iodine (i.e., vial was vigorously shaken), the vial should be vented before being opened.

6.7.1 Create a charcoal trap by placing charcoal in the barrel of a hypodermic syringe between glass-wool plugs.

6.7.2 Fit the syringe with an 18-gauge needle.

6.7.3 Pierce the vial with the needle, penetrating both the septa and the closures.

6.7.4 Slowly remove the needle from the vial.

6.8 Open the vial containing the radioactive iodine for as brief a time as necessary, work quickly, and close tightly when not in use.

6.9 Keep reaction vessels in lead pigs whenever possible.

6.10 Place pipette tips, tubes, etc... used with the unbound radioactive iodine into conical tubes, cap immediately, and discard into the small plastic bag placed in the hood.

6.11 Change the outer pair of gloves as gloves can be easily contaminated upon opening the vial. Dispose of gloves in the small plastic bag placed in the hood.

6.12 After the radioiodination is complete, take down the column.

6.12.1 Remove the column tubing and put the end of the tubing into the top of the column gel.

6.12.2 Seal the iodination columns on both ends with parafilm and wrap in aluminum foil.

6.12.3 Dispose of wrapped columns in the small plastic bag placed in the hood.

6.13 Cap tightly all of the iodinated sample tubes.

6.14 Tightly seal the small plastic bag and discard as radioactive vial waste.

6.15 **Clean-up**

6.15.1 Wipe down the equipment used with Rad-Con surface cleaner.

6.15.2 Remove the disposable absorbent paper from the bottom and sides of the hood and place in a plastic bag as dry waste.

6.15.3 Spray the hood, the hood sill, the hood handle, and the floor in front of the hood with Rad-Con surface cleaner and wipe up with paper towels. Discard the paper towels into the dry waste plastic bag. Repeat.

6.15.4 Discard the dry waste plastic bag as radioactive dry waste into the appropriate trash compactor.

6.16 **Wipe-tests**

6.16.1 Using alcohol wipes (one wipe for each area), wipe the areas designated on the Hood Wipe Tests form (Appendix 1) with moderate pressure, covering at least 100 square cm of the surface (100 square cm is a square approximately 4 inches by 4 inches). Place each wipe in its own counting vial.

6.16.2 Place an unused wipe in another counting vial to be used as a blank, for background determination.

6.16.3 Count the wipes in a gamma counting instrument.

6.17 If any of the wipe-tests are greater than 200 dpm, spray and clean-up the area again with Rad-Con surface cleaner. Repeat the wipe-test.

QA approved 3/28/96 NS

6.17.1 If you are unable to get the area below 200 dpm, contact the Occupational Health and Safety Department.

6.17.2 Label the contaminated area with a sign that states, "Radioactive: Do Not Disturb."

6.18 Record the results of the wipe-tests on the Hood Wipe Tests form taped to the front of the hood.

6.19 Turn off the hood.

6.20 File the printout of the wipe-test data in the laboratory's Radiation Safety Book.

6.21 Make an appointment with the Occupational Health and Safety Department to have a thyroid scan done between 6 hours to 10 days after the radioiodination was completed.

## 7.0 RESULTS

$$\text{DPM} = \frac{\text{Wipe(CPM)} - \text{Background(CPM)}}{\text{Efficiency of the Counter}}$$

## 8.0 QUALITY CONTROL/QUALITY ASSURANCE

Hood Wipe Tests forms and the printouts of the wipe-test data will be reviewed in the quarterly radiation safety audit.

## 9.0 REFERENCES

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 20.1201 (Occupational dose limits for adults). Washington, D.C.: U.S. Government Printing Office, January 1, 1994.

U.S. Department of Energy, Nuclear Regulatory Commission. Regulatory Guide, 8.20 (Applications of bioassay for I-125 and I-131). Washington, D.C.: U.S. Government Printing Office, September 1979.

Shapiro, Jacob. Radiation Protection - A Guide for Scientists and Physicians, 3rd ed. Cambridge, MA: Harvard University Press, 1990.

## 10.0 LIST OF APPENDED MATERIAL

Appendix 1 - Hood Wipe Tests form

WIPE TEST LOG SHEET FOR IODINATION HOOD (5TH FLOOR)

| | Name | Date | Bkgrd | Floor | Sash | Sill | Hood | Tabletop Counter | Comments |
|---|---|---|---|---|---|---|---|---|---|
| Before | | | | | | | | | |
| After | | | | | | | | | |
| Before | | | | | | | | | |
| After | | | | | | | | | |
| Before | | | | | | | | | |
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3026 - 2/96

Appendix I
SOP 10-3420

| TITLE: **Ordering Radioactive Materials** | | |
|---|---|---|
| DEPARTMENT: Occupational Health and Safety | | SOP 10-3404 |
| EFFECTIVE DATE: December 14, 1990 | REV: September 4, 1996 | Page 1 of 2 |

**1.0 PURPOSE/PRINCIPLE**

To provide instructions for ordering radioactive materials.

**2.0 SPECIAL NOTES**

2.1 A completed and approved Laboratory Procedures Using Radioactive Isotopes form for the isotope being ordered must be on file in the Occupational Health and Safety Department.

2.2 Materials Management will not accept a Purchase Requisition For Materials form for a radioactive isotope without the radiation safety approval stamp and the signature of one of the individuals listed in Appendix 1.

2.3 Staff trained in radiation safety must be available in the department to check in the package on the date the package is expected.

**3.0 MATERIALS REQUIRED** - N/A

**4.0 EQUIPMENT REQUIRED** - N/A

**5.0 RECORDS**

Purchasing Requisition For Materials form

A copy of the Purchasing Requisition For Materials form will be retained by the Occupational Health and Safety Department or Research Administration until the radioactive material has been received and checked in.

**6.0 PROCEDURE**

6.1 Complete the Purchasing Requisition For Materials form including the isotope, chemical form, quantity, and required by date (Appendix 2) .

6.2 Submit the Purchasing Requisition For Materials form to the Authorized User for review and approval signature.

6.3 Submit the signed Purchasing Requisition For Materials form to either the Occupational Health and Safety Department at headquarters or Research Administration at the Blood Research Institute for review and approval.

6.4 Send the Purchasing Requisition For Materials form to Materials Management.

6.5 During review, one of the individuals authorized to approve the purchase of a radioactive material will do the following:

6.5.1 Review the Purchase Requisition For Materials form and confirm that the requisition was completed correctly with the isotope, chemical form, quantity, and the signature of the Authorized User.

6.5.2 Confirm that a Laboratory Procedures Using Radioactive Isotopes form for that isotope is on file in the Occupational Health and Safety Department.

6.5.3 Check to ensure that the quantity of the isotope being requested does not exceed the maximum amount The Blood Center may possess at any one time as stated in The Blood Center's NRC Materials License, # 48-02000-01.

6.5.4 When all these conditions are met, stamp the Purchase Requisition For Materials form "Approved Radiation Safety" and sign your name near the stamp.

6.5.5 For packages being received by Sample Management, send an E-mail to Sample Management and the supervisor of Clinical Laboratory Administration notifying them that a radiation package has been ordered, by whom, and the expected date of delivery.

**7.0 RESULTS** - N/A

**8.0 QUALITY CONTROL/QUALITY ASSURANCE** - N/A

**9.0 REFERENCES**

U.S. Department of Energy, Nuclear Regulatory Commission, Code of Federal Regulations, Title 10, Part 20.1101 (Radiation Protection Programs). Washington, D.C.: U.S. Government Printing Office, 1995.

**10.0 LIST OF APPENDED MATERIAL**

Appendix 1 - Individuals Authorized to Approve the Purchase of Radioactive Materials
Appendix 2 - Purchasing Requisition For Materials form
Appendix 3 - Radiation safety approval stamp

**Individuals Authorized to Approve the Purchase of Radioactive Materials**

| | |
|---|---|
| Nancy Drzewiecki | Supervisor, Occupational Health and Safety |
| Mary Pawlak | Supervisor, Research Operations |
| Laura Schloesser | Safety Coordinator, Occupational Health and Safety |
| Nancy Schunk | Manager, Quality Assurance and Safety |
| Nancy Szatkowski | Supervisor, Research Operations |

Acceptable alternates when the above individuals are not available:

| | |
|---|---|
| Marcia Iverson | Supervisor, Research Administration |
| Chris Miller | Manager, Research Administration |
| Sandra Zalewski | Program Assistant, Quality Assurance and Safety |

The Blood Center of Southeastern Wisconsin

**PURCHASING REQUISITION FOR MATERIAL**

| CHECK APPROPRIATE BOX(ES) | | FOR OFFICE USE ONLY | |
|---|---|---|---|
| P.O. No. | DATE REQUESTED: 8-20-96 | [X] Phone Order In: # 1-800-555-1234<br>[ ] Mail Order In<br>[ ] Fax Order In: # | DATE PHONED IN | BY |

| QUANTITY | UNIT OF ISSUE | DESCRIPTION/CATALOG # | DELIVER TO* | UNIT PRICE | FOR OFFICE USE ONLY | COST CENTER | ACCOUNT |
|---|---|---|---|---|---|---|---|
| 1 | EA | 5.0 mCi $^{125}$I Sodium Iodide. Cat.# 1234AB | Lab A | | | | |
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| | | | | | | | |
| | | | | # of Req's | Total Req | Total Order | |

| | | |
|---|---|---|
| Company: Roentgen Corp. | Requested by: L. Employee Ext. 9876 | CAPITAL EXPEND INFORMATION REQUIRED |
| Address: 789 Curie Ave. | Supervisor ($3,000): | Acct. # from Capital Exp. Plan: 20-9999-_____-999 |
| City: Anywhere | Manager ($5,000): Arthur Z. User | Cap. Exp. #: |
| State: WI | Vice President ($10,000): | Department CC #: |
| ZIP: 54567 | President or Exec. Vice Pres. ($25,000): | |
| REQUIRED BY DATE: 8-22-96 | President & Exec. Vice Pres. (over $25,000): | Equip. for: |

*Deliver to is: lab name or department name

FMM11-2/94

78-820

Appendix 2
SOP# 10-3404

APPROVED
Radiation Safety

| TITLE: **Radioactive Material Package Receipt - Headquarters** QA approved 4/12/96 NS | |
|---|---|
| DEPARTMENT: Occupational Health and Safety | SOP 10-3405 |
| EFFECTIVE DATE: May 26, 1994 REV: December 18, 1995 | Page 1 of 2 |

**1.0 PURPOSE/PRINCIPLE**

To provide instructions for receiving packages containing radioactive materials at The Blood Center headquarters facility.

**2.0 SPECIAL NOTES**

2.1 All packages containing radioactive materials will be delivered by the carrier to Sample Management.

2.2 During regular working hours, Sample Management will receive packages containing radioactive materials. Administrative secretaries in Clinical Laboratory Administration will provide back-up. Individuals must have radiation safety training prior to performing this procedure.

2.3 After regular working hours, packages containing radioactive materials are received by the Customer Service Department. See SOP 12-2021.

2.4 When a radioactive material is ordered, Occupational Health and Safety will send an E-mail message to Sample Management and to the supervisor of Clinical Laboratory Administration, indicating the name of the person and laboratory ordering the radioactive material, the type of radioactive material ordered, the company the radioactive material is ordered from, and the expected delivery date.

**3.0 MATERIALS REQUIRED** - N/A

**4.0 EQUIPMENT REQUIRED** - N/A

**5.0 RECORDS**

Packing Slip
*Form Q* (if needed)

**6.0 PROCEDURE**

6.1 Meet the carrier and examine the package prior to accepting it. Visually inspect the package for damage, e.g. wetness, collapse, puncture.

6.2 If it appears damaged, do not accept the package.

6.2.1 If you have not yet touched the package, leave it where it is. Do not touch or move it. If you are already holding the package, place the package immediately down on the floor out of the traffic path. Avoid carrying the package any distance. Avoid spreading possible contamination by eliminating hand contact with other objects.

6.2.2 Explain to the carrier that he/she must wait until we can be sure that there is no radioactive contamination present in his vehicle.

6.2.3 Contact one of the individuals listed in Appendix 1.

6.2.4 If you have touched the package, wash your hands. To avoid spreading possible contamination, ask someone to take you to the sink, open doors, turn on the faucet, etc.

6.2.5 Place a sign on top of the package that states, "Radioactive Materials: Do Not Disturb."

6.3 If the package is not damaged, accept it from the carrier and sign for it.

6.4 Immediately call the individual and/or laboratory that ordered the package. (This information is generally on the packing slip; however, it may require checking with Materials Management or Occupational Health and Safety.)

6.5 Log the package information onto the Sample Management Services - Sample Log Sheet.

6.6 Ask the person in the lab who accepts the package to sign the log sheet, inform him or her that the package contains radioactive materials and remind him or her to secure the package.

6.7 If there is no one available in the ordering laboratory to pick up the radioactive package, secure the package in the designated cabinet under the chemical fume hood on the fifth floor. This cabinet is to be kept locked at all times.

6.7.1 Notify the ordering lab as soon as possible by audix or E-mail, with a follow up phone call, that a package containing radioactive materials has been received, and where it is located.

6.7.2 When someone from the ordering lab contacts you, either deliver the package or ask him or her to meet you by the hood on the fifth floor and transfer the package there.

6.8 If the package is not picked up within 3 hours after the package is received and the ordering laboratory does not respond to any of the messages sent, please contact the Occupational Health and Safety Department.

## 7.0 RESULTS - N/A

## 8.0 QUALITY CONTROL/QUALITY ASSURANCE

*Form Qs* will be completed for damaged packages and reviewed by the Supervisor of Occupational Health and Safety in order to identify and deal with any problem trends that may occur.

## 9.0 REFERENCES

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 20.205 (Procedures for picking up, receiving, and opening packages). Washington, D.C.: U.S. Government Printing Office, January 1, 1993.

## 10.0 LIST OF APPENDED MATERIAL

Appendix 1 - Emergency Contact People

Emergency Contact People
Radioactive Material Package Receipt - Headquarters

| Name | Department | Extension |
|---|---|---|
| Nancy Drzewiecki | Occupational Health & Safety | X 6380, Beeper 777-6634 |
| Laura Schloesser | Occupational Health & Safety | X 6381 |
| Nancy Schunk | Quality Assurance & Safety | X 6225 |
| Loni Kagen | Transfusion Medicine Laboratory | X 6244 |
| Kevin Zold | Paternity Testing Laboratory | X 6320 |
| Jim Kaliszewski | Platelet Antibody Laboratory | X 6255 |

| TITLE: Radioactive Package Check-In at Headquarters | | |
|---|---|---|
| DEPARTMENT: Occupational Health and Safety | | SOP 10-3406 |
| EFFECTIVE DATE: August 29, 1994 | REV: June 15, 1996 | Page 1 of 3 |

## 1.0 PURPOSE/PRINCIPLE

To provide instructions for checking-in packages containing radioactive materials that are received at The Blood Center headquarters.

The Nuclear Regulatory Commission (NRC) has established federal regulations governing the procedures used for receiving radioactive packages. The objective of these regulations is to identify, reduce, and eliminate the exposure and contamination of individuals who come in contact with radioactive packages. By following this procedure, packages with radioactive contamination on their external surfaces will be identified quickly and unnecessary exposure to employees will be prevented.

## 2.0 SPECIAL NOTES

2.1 Federal regulations require that package check-in be performed as soon as practicable after receipt of the package, but not more than 3 hours after the package is received at The Blood Center if it is received during normal working hours, or not more than 3 hours from the beginning of the next working day if it is received after normal working hours.

2.2 Gloves, lab coats, and radiation detection badges must be worn when checking in packages that contain radioactive materials. Thermoluminescent dosimeter (TLD) rings must be worn when checking in packages that contain $^{32}P$ or $^{51}Cr$.

2.3 Radiation safety training is required to perform this procedure.

2.4 The Maximum Permissible Limits on a wipe is 22 disintegrations per minute (dpm)/$cm^2$ above background. If the wipe exceeds this limit, the Radiation Safety Officer will immediately notify the final delivery carrier and, by telephone and by telegram, the Administrator of the U.S. Nuclear Regulatory Commission, Region III, office.

## 3.0 MATERIALS REQUIRED

Premoistened alcohol wipes
Counting vials
Scintillation cocktail (for beta isotope counting)

## 4.0 EQUIPMENT REQUIRED

Beta or gamma counting instrument
Utility knife
Permanent black ink marker
Geiger-Mueller counter

## 5.0 RECORDS

Printout of wipe test data
Packing slip
Manufacturer's data sheet
Form Q (if necessary)

## 6.0 PROCEDURE

6.1 Visually inspect the exterior of the package for wetness or damage, i.e., collapse or puncture.

6.1.1 If the package appears damaged, do not handle it further. Notify your supervisor

or the Occupational Health and Safety Department immediately.

6.2 If the package is not damaged, remove the packing slip and note the isotope.

6.3 Using one of the alcohol wipes, wipe with moderate pressure over the exterior surface of the package, covering at least 100 square cm of the exterior surface (100 square cm is a square approximately 4 inches by 4 inches). Place the wipe in a counting vial.

6.4 Place the second, unused wipe in another counting vial to be used as a blank, for background determination.

6.5 If the package contains a beta-emitting isotope, place enough scintillation cocktail in the vials to completely cover the wipe. Cap and shake the vial.

6.6 Count the wipes in the appropriate counting equipment, i.e., beta or gamma counter.

6.7 Retrieve the printout of data, sign and date it, and note the laboratory where the radioactive material is to be used.

6.8 If the wipe test count exceeds 200 dpm, the package may be contaminated. Do not handle the package any further.

6.8.1 Notify your laboratory supervisor and the Occupational Health and Safety Department immediately.

6.9 If the package contains a quantity of radioactive material greater than the amount indicated below, the package must be surveyed with a Geiger-Mueller counter:

| | |
|---|---|
| $^{14}C$ | 5,400 µCi |
| $^{45}Ca$ | 2,430 µCi |
| $^{51}Cr$ | 81,100 µCi |
| $^{59}Fe$ | 2,160 µCi |
| $^{3}H$ | 108,000 µCi |
| $^{203}Hg$ | 2,430 µCi |
| $^{125}I$ | 5,400 µCi |
| $^{131}I$ | 1,350 µCi |
| $^{111}In$ | 5,400 µCi |
| $^{32}P$ | 810 µCi |
| $^{35}S$ | 5,400 µCi |

6.9.1 Survey the package at three feet away from the package (background reading) and at the surface of the package.

6.9.2 If the external radiation level monitored at the surface of the package exceeds the following radiation levels as indicated by the type of radioactive label on the package (Appendix 1), it may be contaminated. Do not handle the package any further.

| Label Type | Radiation Level (RL) at Package Surface in milliRoentgens/hour (mR/hr) |
|---|---|
| White I | RL ≤ 0.5 mR/hr |
| Yellow II | 0.5 mR/hr < RL ≤ 50 mR/hr |
| Yellow III | RL > 50 mR/hr |

6.9.2.1 Notify your supervisor and the Occupational Health and Safety Department immediately.

6.9.3 Write the background and surface radiation levels monitored on the packing slip along with the date and your initials.

6.10 If the wipe test exhibits no contamination, open the package and compare its contents to the packing slip.

6.10.1 If the contents of the packing slip do not match the contents of the package, contact the manufacturer immediately to determine the correct information.

6.11 Return the packing slip with the attached wipe test data and manufacturer's data sheet to the Occupational Health and Safety Department. A Record of Radioactive Materials Use form will be generated and sent to you by interoffice mail.

6.12 Remove all radioactive stickers and/or obliterate all radioactive signs on the package with a black permanent marker and dispose of as regular trash.

6.13 Place radioactive material in properly labeled radioactive storage area.

## 7.0 RESULTS - N/A

## 8.0 QUALITY CONTROL/QUALITY ASSURANCE

The Occupational Health and Safety Department will verify that the wipe tests, and, when necessary, the Geiger-Mueller counter surveys, have been performed before generating a Record of Radioactive Materials Use form for the laboratory.

## 9.0 REFERENCES

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 20.1906 (Procedures for receiving and opening packages). Washington, D.C.: U.S. Government Printing Office, January 1, 1995 to date.

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 71.87 (Routine determinations - Table V - Removable External Radioactive Contamination Wipe Limits), and Part 71, Appendix A - Determination of $A_1$ and $A_2$. Washington, D.C.: U.S. Government Printing Office, January 1, 1995 to date.

## 10.0 LIST OF APPENDED MATERIAL

Appendix 1 - Samples of Radioactive White I, Yellow II and Yellow III Labels.

**Examples of Shipping Labels for Radioactive Materials**

Radioactive White-I Label:


Radioactive Yellow-II Label:


Radioactive Yellow-III Label:

| TITLE: **Radioactive Package Receipt and Check-in at the Blood Research Institute** | | |
|---|---|---|
| DEPARTMENT: Research Administration | | SOP 14-0002 |
| EFFECTIVE DATE: August 22, 1994 | REV: August 15, 1996 | Page 1 of 4 |

## 1.0 PURPOSE/PRINCIPLE

To provide instructions for receiving and checking in packages containing radioactive materials that are sent to the Blood Research Institute.

The Nuclear Regulatory Commission (NRC) has established federal regulations governing the procedures used for receiving radioactive packages. The objective of these regulations is to identify, reduce, and eliminate the exposure and contamination of individuals who come in contact with radioactive packages. By following this procedure, packages with radioactive contamination on their external surfaces will be identified quickly and unnecessary exposure to employees will be prevented.

## 2.0 SPECIAL NOTES

2.1 Federal regulations require that package check-in be performed as soon as practicable after receipt of the package, but not more than 3 hours after the package is received at the Blood Research Institute if it is received during normal working hours, or not more than 3 hours from the beginning of the next working day if it is received after normal working hours.

2.2 Gloves, lab coats, and radiation detection badges must be worn when checking in packages that contain radioactive materials. Thermoluminescent dosimeter (TLD) rings must be worn when checking in packages that contain $^{32}P$ or $^{51}Cr$.

2.3 Radiation safety training is required to perform this procedure.

2.4 The Maximum Permissible Limits on a wipe is 22 disintegrations per minute (dpm)/$cm^2$. If the wipe exceeds this limit, the Radiation Safety Officer will immediately notify the final delivery carrier and, by telephone and by telegram, the Administrator of the U.S. Nuclear Regulatory Commission, Region III, office.

2.5 NCR regulations require that you **first** check for external physical radiation leaks by performing a wipe test so that the driver can be quickly notified and his vehicle checked. The Geiger-Mueller scan is performed to check for internal leaks. This check notifies the user that the package may have leaked inside, but the contamination has not reached the surface of the box.

## 3.0 MATERIALS REQUIRED

Premoistened alcohol wipes (MM #01-063)
Scintillation vials with caps (MM #03-753)
Scintillation cocktail (for beta isotopes counting)

## 4.0 EQUIPMENT REQUIRED

Beta or gamma counting instrument
Utility knife
Permanent black ink marker
Geiger-Mueller counter

## 5.0 RECORDS

Printout of wipe test data
Packing slip
Manufacturer's data sheet

*Form Q* (if necessary)

## 6.0 PROCEDURE

6.1 Receiving Radioactive Packages

6.1.1 Upon receipt, maintenance personnel, the supervisor of Research Laboratory Operations, Research Administration or laboratory personnel will visually inspect the exterior of the package for wetness or damage, i.e., collapse or puncture prior to accepting it.

6.1.2 If package appears damaged, do not handle it further. Do not accept the package from the Courier.

6.1.2.1 If you have not yet touched the package, leave it where it is. Do not touch or move it. If you are already holding the package, immediately place it down out of the way of personnel. Avoid carrying the package any distance. Avoid spreading possible contamination by eliminating hand contact with other objects.

6.1.2.2 Explain to the carrier that he/she must wait until we can be sure that there is no radioactive contamination present in his/her vehicle.

6.1.2.3 Go to the receptionist desk, guard station, or other staff who can assist, and inform them that you have a damaged radioactive package and to contact the supervisor of Research Laboratory Operations or one of the individuals listed in Appendix 1.

6.1.3 If the package is not damaged, sign for the package and call the receptionist in Research/Administration at ext. 3897 to tell her that a radioactive package has arrived.

6.1.4 Put the package in one of the radioactive storage cabinets and lock it with the key that is located on the hook underneath the lower radioactive storage cabinet.

6.1.5 The receptionist is responsible for notification of the individual who ordered the package so that he/she (or his/her designee) can check-in the package. This should be done through a phone call, as well as electronic mail.

6.2 Checking-in Radioactive Packages

6.2.1 Unlock the cabinet with keys located on the hook underneath the radioactive cabinet, remove the packing slip from the package and note the isotope.

6.2.2 Using one of the alcohol wipes, wipe with moderate pressure over the exterior surface of the package, covering at least 100 square cm of the exterior surface (100 square cm is a square approximately 4 inches by 4 inches). Place the wipe in a counting vial.

6.2.3 Place the second, unused wipe in another counting vial to be used as a blank for background determination.

6.2.4 If the package contains a beta-emitting isotope, place enough scintillation cocktail in the vials to completely cover the wipe. Cap and shake the vial.

6.2.5 Count the wipes in the appropriate equipment, i.e, beta or gamma counter.

6.2.6 Retrieve the printout of data with the date and time, sign it, and note the laboratory where the radioactive material is to be used.

6.2.7 If the wipe test count exceeds 200 dpm, the package may be contaminated. Do not handle the package any further.

6.2.7.1 Notify the supervisor of Research Laboratory Operations and/or the Occupational Health and Safety Department.

6.2.8 If the package contains a quantity of radioactive material greater than the amount indicated below, the package must be surveyed with a Geiger-Mueller counter:

| | |
|---|---|
| $^{14}C$ | 5,400 µCi |
| $^{45}Ca$ | 2,430 µCi |
| $^{51}Cr$ | 81,100 µCi |
| $^{59}Fe$ | 2,160 µCi |
| $^{3}H$ | 108,000 µCi |
| $^{203}Hg$ | 2,430 µCi |
| $^{125}I$ | 5,400 µCi |
| $^{131}I$ | 1,350 µCi |
| $^{111}I$ | 5,400 µCi |
| $^{32}P$ | 810 µCi |
| $^{35}S$ | 5,400 µCi |

6.2.8.1 Survey the package at three feet away from the package (background reading) and at the surface of the package.

6.2.8.2 If the external radiation level monitored at the surface of the package exceeds the following radiation levels as indicated by the type of radioactive label on the package (Appendix 2), it may be contaminated. Do not handle the package any further.

| Label Type | Radiation Level (RL) at Package Surface in milliRoentgens/hour (mR/hr) |
|---|---|
| White I | RL ≤ 0.5 mR/hr |
| Yellow II | 0.5 mR/hr < RL ≤ 50 mR/hr |
| Yellow III | RL > 50 mR/hr |

6.2.8.2.1 Notify the supervisor of Research Laboratory Operations and the Occupational Health and Safety Department immediately.

6.2.8.3 Write the background and surface radiation levels monitored on the

packing slip along with the date and your initials.

6.2.9 If the wipe test exhibits no contamination, open the package and compare its contents to the packing slip.

6.2.9.1 If the contents of the packing slip do not match the contents of the package, contact the manufacturer immediately to determine the correct information.

6.2.10 Return the packing slip with the attached wipe test data and manufacturer's data sheet to the supervisor of Research Laboratory Operations. A record of Radioactive Materials Use sheet will be generated and sent to you by interoffice mail.

6.2.11 Remove all radioactive stickers and/or obliterate all radioactive signs on the package with a black permanent marker and dispose of as regular trash.

6.12 Place radioactive material in properly labelled radioactive storage area.

**7.0 RESULTS** - N/A

**8.0 QUALITY CONTROL/QUALITY ASSURANCE**

8.1 The supervisor of Research Laboratory Operations or Occupational Health & Safety Department will verify that wipe tests, and, when necessary, the Geiger-Mueller counter surveys, have been performed before generating a Record of Radioactive Materials Use form for the laboratory.

8.2 To ensure that packages are processed, the receptionist or his/her designee check the cabinets at approximately 10 a.m., 2 p.m., and 4 p.m.

**9.0 REFERENCES**

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 20.1906 (procedures for receiving and opening packages). Washington, D.C.: U.S. Government Printing Office, January 1, 1995 to date.

U.S. Department of Energy, Nuclear Regulatory Commission. Code of Federal Regulations, Title 10, Part 71.87 (Routine determinations - Table V - Removable External Radioactive Contamination Wipe Limits), and Part 71, Appendix A - Determination of $A_1$ and $A_2$. Washington, D.C.: U.S. Government Printing Office, January 1, 1995 to date.

**10.0 LIST OF APPENDED MATERIAL**

Appendix 1 - List of Emergency Contact People
Appendix 2 - Samples of Radioactive White I, Yellow II and Yellow III Labels

EMERGENCY CONTACT PEOPLE
RADIOACTIVE MATERIAL PACKAGE RECEIPT

| Name | Department | Extension/Number |
|---|---|---|
| Mary Pawlak | Research Administration | 3847 |
| Nancy Szatkowski | Research Administration | 3847 |
| Nancy Drzewiecki | Occupational Health & Safety | 6380, beeper 777-6634 |
| Laura Schloesser | Occupational Health & Safety | 6381 |
| Nancy Schunk | Quality Assurance & Safety | 6225 |

# Examples of Shipping Labels for Radioactive Materials

Radioactive White-I Label:


Radioactive Yellow-II Label:



Radioactive Yellow-III Label:

Attachment F

**Quarterly Radiation Safety Audit**
**The Blood Center of Southeastern Wisconsin, Inc.**

Peptide Immunology
Authorized User: Debra Newton-Nash, Ph.D.

**Surveys**
Reading: Instrument Used:

**Wipe Tests**
$^{3}H$

| Date | Beta | Gamma | Comments |
|---|---|---|---|
| 06/10/96-06/16/96 | | | |
| 06/17/96-06/23/96 | | | |
| 06/24/96-06/30/96 | | | |
| 07/01/96-07/07/96 | | | |
| 07/08/96-07/14/96 | | | |
| 07/15/96-07/21/96 | | | |
| 07/22/96-07/28/96 | | | |
| 07/29/96-08/04/96 | | | |
| 08/05/96-08/11/96 | | | |
| 08/12/96-08/18/96 | | | |
| 08/19/96-08/25/96 | | | |
| 08/26/96-09/01/96 | | | |
| 09/02/96-09/08/96 | | | |
| ---------- | | | |
| ---------- | | | |

Contact Person: Kathleen Kennedy

_____
Signature and Date

**RSO Report**
**The Blood Center of Southeastern Wisconsin**
**June 24, 1996**

A. Training 16 sessions/45 employees

1. March 22, 1996 - Annual training for Security (3)
2. April 2, 1996 - Irradiator training for new employees in Transfusion Services (10)
3. April 5, 1996 - Annual training for Facilities Management (2)
4. April 16, 1996 - New employee in Clinical Labs (1)
5. May 1, 1996 - New employees in Research (2)
6. May 3, 1996 - Annual training make-up for Paternity (1)
7. May 14, 1996 - New employee in Clinical Labs (1)
8. May 17, 1996 - Annual training for Research Administration (8)
9. May 30, 1996 - Irradiator training for new employee in Transfusion Services (1)
10. June 3, 1996 - Annual training for Clinical Lab Admin (2) and Sample Management (1)
11. June 4, 1996 - New employees in Research (2) and Clinical Labs (2)
12. June 5, 1996 - Irradiator training for new employee in Customer Service (1)
13. June 6, 1996 - New contract employee in Facilities Management (1)
14. June 10, 1996 - Annual training for Clinical Lab Admin (3)
15. June 11, 1996 - New employees in Research (2)
16. June 12, 1996 - New employees in Clinical Labs (2)

B. Personnel Exposures

1. Dosimeters (February, March, April)

Annual Limits Whole body - 5,000 mrems
Skin or any extremities - 50,000 mrems

Film badge range: 0 - 10 mrem
TLD ring range: 0 - 80 mrem

2. Bioassays

Reportable limit 120 nCi
Thyroid scans range: 0 - 0.8 nCi

C. Activity/Incident Report

No incidents to report.

D. Wipe Test Book Audits

Histocompatibility: missing 3 weeks of wipe test documentation over a 13 week time period. David Eckels, Authorized User

E. Irradiator Leak Checks

1. June 13, 1996 - Leak testing on the headquarters irradiator performed. Results were below permissible limits.

2. June 14, 1996 - Leak testing on the BRI irradiator performed. Results were below permissible limits.

F. Equipment Calibration

Four survey meters and two scaler ratemeters have been calibrated since the last meeting; all active meters have been calibrated within the last 12 months.

G. Effluent Monitoring

1. Air effluent monitored for $^{125}I$ monthly: March, April, and May at BRI and headquarters. All readings were below permissible limits.

2. 1996 first quarter discharge to sanitary sewer summary

| Isotope | Quarterly Discharge | Annual Limit |
|---|---|---|
| $^{3}H$ | 4.0 mCi | 5000 mCi |
| $^{14}C$ | 0.03 mCi | 1000 mCi |
| $^{32}P$ | 6.0 mCi | -- |
| $^{35}S$ | 4.1 mCi | -- |
| $^{111}In$ | 2.2 mCi | -- |
| $^{125}I$ | 0.8 mCi | -- |

H. Quarterly Surveys

1. Survey readings for all areas where radioactive materials are used or stored are completed.

2. Readings for dosimeters placed in locations to prove that we are not exposing members of the public to radiation were zero for the first quarter of 1996.

Audits performed by:

Nancy Schunk

Nancy Schunk
Radiation Safety Officer
Manager, Quality Assurance and Safety

Nancy Drzewiecki

Nancy Drzewiecki
Supervisor, Occupational Health and Safety

## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER AND RSO

**Name:** Nancy A. Drzewiecki

**Education:** B.S. in Molecular Biology/Biochemistry, May 1991

**Training in Basic Radioisotope Handling Techniques:**

*Field: Radiation Physics and Instrumentation*
University of Wisconsin-Milwaukee, Milwaukee
Marquette University, Milwaukee
Courses in Physics, Analytical Chemistry and Physical Chemistry, 3 hours x 6
Radiation Safety Officer Course, Engelhardt & Associates, Inc., Madison, Wisconsin, October 16-20, 1995

*Field: Radiation Protection*
Marquette University, Milwaukee
Medical College of Wisconsin, Milwaukee
The Finch University of Health Sciences/The Chicago Medical School
The Blood Center of Southeastern Wisconsin, On-the-Job Training
Radiation Safety Officer Course, Engelhardt & Associates, Inc., Madison, Wisconsin, October 16-20, 1995

*Field: Mathematics in the Use/Measurement of Radioactivity*
University of Wisconsin-Milwaukee, Milwaukee
Calculus courses, 3 hours x 4
Radiation Safety Officer Course, Engelhardt & Associates, Inc., Madison, Wisconsin, October 16-20, 1995

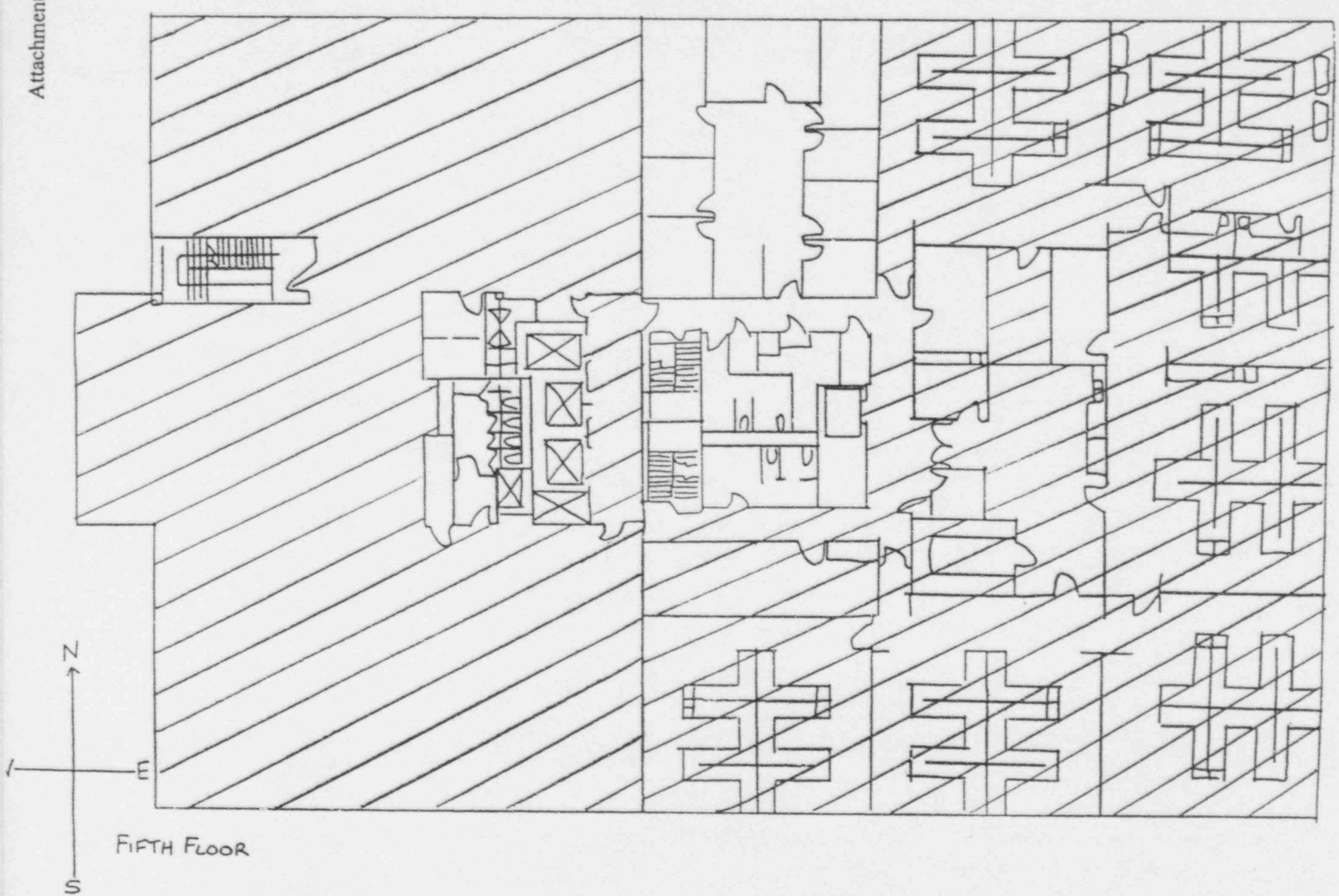
*Field: Radiation Biology*
Medical College of Wisconsin, Milwaukee
The Finch University of Health Sciences/The Chicago Medical School
The Blood Center of Southeastern Wisconsin, On-the-Job Training
Radiation Safety Officer Course, Engelhardt & Associates, Inc., Madison, Wisconsin, October 16-20, 1995

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{32}P$ | 10 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{35}S$ | 4 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{125}I$ | 20 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{3}H$ | 2 mCi | Medical College of Wisconsin | 2 years | Research |
| | | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{51}Cr$ | 5 mCi | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{14}C$ | 1 mCi | Blood Center of Southeastern WI | 2 years | Radiation Safety |
| $^{111}In$ | 1 mCi | Blood Center of Southeastern WI | 1 year | Radiation Safety |
| $^{45}Ca$ | 1 mCi | Blood Center of Southeastern WI | 1 year | Radiation Safety |

Attachment I

The Blood Center of Southeastern Wisconsin
Headquarters
638 North 18th Street
Fifth Floor



## 8. TRAINING AND EXPERIENCE - AUTHORIZED USER

**Name:** Janice G. McFarland, M.D.

**Education:** Blood Banking, American Board of Pathology, 6/85
Hematology, American Board of Internal Medicine, 9/82
Internal Medicine, American Board of Internal Medicine, 9/80
Licensed to practice Medicine in Wisconsin

**Training in Basic Radioisotope Handling Techniques and Supervised Clinical Experience:**

*Field: Radiation Physics and Instrumentation*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4 hrs/week x 6 weeks; Clinical rotation, 6 weeks

*Field: Radiation Protection*
University of Washington, Seattle, 1980-1983
Radiation Safety Course, 3 hrs; Supervised Laboratory Experience, 2 years
The Blood Center of Southeastern Wisconsin
Radiation Safety Training, 1 hr x 6

*Field: Mathematics in the Use/Measurement of Radioactivity*
University of Oregon, Eugene, 1969-1973
Physics Course, 9hrs; Laboratory, 4 hrs

*Field: Radiation Biology*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4 hrs/week x 6 weeks; Clinical rotation, 6 weeks
The Blood Center of Southeastern Wisconsin
Radiation Safety Training, 1 hr x 6

*Field: Radiopharmaceutical Chemistry*
University of Oregon Health Science Center, Portland, 1973-1977
Radiation Oncology, 4 hrs/week x 6 weeks; Clinical rotation, 6 weeks

**Experience with Radiation:**

| Isotope | Max Amt | Institution | Duration | Type |
|---|---|---|---|---|
| $^{125}I$ | 5 mCi | University of Washington, Seattle<br>Blood Center of Southeastern WI | 6 years | Research & Clinical Testing |
| $^{51}Cr$ | 10 mCi | Blood Center of Southeastern WI | 5 years | Research & Clinical Testing |
| $^{14}C$ | 1 mCi | Blood Center of Southeastern WI | 3 years | Research & Clinical Testing |

May 2, 1995

Blood Center of Southeastern Wisc
ATTN: Nancy J. Schunk
Radiation Safety Officer
P.O. Box 2178
Milwaukee, WI 53201-2178

SUBJECT: LICENSE RENEWAL APPLICATION

Dear Mr. Schunk:

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

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

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Section

License No. 48-02000-01
Control No. 398510

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| OFFICE | DRSS/RIII | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| NAME | MMEENAN:brt | MM | | | | | | |
| DATE | 05/2/95 | | | | | | | |

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