NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

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:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 37-09752-01

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

Department of Health & Human Services
US Food and Drug Administration
Room 900, U.S. Customhouse, 2nd & Chestnut Sts.
Philadelphia, PA 19106

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

US Food and Drug Administration
Science Branch
US Customhouse, 2nd & Chestnut Sts.
Philadelphia, PA 19106

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Richard E. Needham, Supervisory Chemist/Radiation Safety Officer | (215)597-2123

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. see attached Item #5

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. see attached Item #6

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. see attached Item #7

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

9. FACILITIES AND EQUIPMENT. see attached Item #9

10. RADIATION SAFETY PROGRAM. see attached Item#10

11. WASTE MANAGEMENT. see attached Item #11

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY N/A | AMOUNT ENCLOSED $ Exempt U.S. Gov't Agency

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, 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.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Harvey M. Miller	Harvey M. Miller	Director, Science Branch	12/29/88

FEE EXEMPT

FOR NRC USE ONLY

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

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5, 6. Radioactive Materials and Purposes for which Materials will be Used

Radionuclide	Chemical/ Physical Form	Maximum Amount to be Used	Intended Uses
3-Hydrogen	Tritiated Peptides, Tritiated Biomolecules	20 mCi (7.40×10^8 Bq)	Research, Tracers Regulatory Analysis: In-Vitro Diagnostics
32-Phophorus	Phosphoric Acid & Salts, Labeled Nucleotides	10 mCi (3.70×10^8 Bq)	Research/Tracers DNA Probe Research
35-Sulfur	Sulfuric Acid & Salts, Labeled Nucleotides	20 mCi (7.40×10^8 Bq)	Research/Tracers DNA Probe Research
63-Nickel	Foils & Electro-plated Sources	30 mCi (1.11×10^9 Bq)	Gas Chromatographic Electron-Capture Detectors
125-Iodine	Sodium Iodide Solutions (pH > 8.0), Iodinated Proteins & Biochemicals	50 mCi (1.85×10^9 Bq)	Research/Tracers Regulatory Analysis: In-Vitro Diagnostics

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

A. Edmond J. Baratta, Radiation Safety Officer, Food and Drug Administration, Winchester Engineering and Analytical Center, Winchester, Massachusetts will serve as off-site Radiation Safety Officer and will serve as consultant as required.

B. Richard E. Needham, Supervisory Chemist, Food and Drug Administration, Philadelphia District Office, Philadelphia, PA will serve as the on-site Radiation Safety Officer.

C. Statements of Professional Experience and Training for the off-site and on-site Radiation Safety Officer follow on the next two pages.

CURRICULUM VITAE

Name : Edmond J. Baratta
5 Fairlane Terrace
Winchester, MA 01890

Education : Washington and Jefferson College
Boston University
B.S. Chemistry - Northeastern University
Boston, MA - 1953

Experience : Shell Oil Company, Houston, TX - 1963-1956
Quality Control and Testing of Petroleum Products

U. S. Navy, Newport, RI - 1957-1959
Quality Control and Testing of Petroleum Products

National Lead Company, Winchester, MA - 1959-1961
Research and Development of Methods for Low-level analysis of uranium tailings and raffinates

Public Health Service, Bureau of Radiological Health, Winchester, MA - 1961-1970
Environmental Protection Agency, Office of Radiation Programs, Winchester, MA - 1970-1972
Responsible activities were:

(a) Chief of the Analytical Services Program involved in the research and development of methods for testing nuclear weapons fallout. Training of analysts both Federal and State in the analyses of various materials such as air, food, water, soil, biota, etc. for natural-occurring and artifically produced radionuclides.

(b) Quality control and testing of various products for natural-occurring and artifically produced radionuclides.

(c) Chief of the Analytical Quality Control Service, first with BRH and later with EPA. It provided quality assurance samples, low-level radionuclide standards and other service to Federal, State, International Agencies and the nuclear industry and its contractors.

(d) Member of the Facilities Radiation Safety Committee as a principle user.

Public Health Service, Food and Drug Administration, Office of Regulatory Affairs, Winchester Engineering and Analytical Center, Winchester, MA - 1972 to Present

(a) National Expert, Radioactivity - Consultant for the FDA in the area of radioactivity including, but not limited to, radionuclide analyses and radiopharmaceutical products.

(b) Chief of the Radionuclide Section which performs quality assurance and testing of radiopharmaceutical products and radionuclides in foods. Includes development and research in these areas.

(c) Radiation Safety Officer, WEAC, since 1986, member of Radiation Safety Committee prior to this as a principle user. Member FDA Radiation Safety Committee.

Qualifications and Skills :

(a) Consultant to the Atomic Energy Agency, Pan American Health Organization and Food and Agricultural Organization

(b) Expert Advisor to the Saudi-Arabian Government on Radioactivity

(c) General Referee, Radioactivity for the Association of Official Analytical Chemists

(d) Member ANSI N42.2 Subcommittee

(e) Fellow of the Association of Official Analytical Chemists - 1983

(f) Plenary Member, Health Physics Society

(g) President, Executive Board Member, Northeastern Section, Association of Official Analytical Chemists 1987-1988

(h) Advisor to the APHA for the 12th and 13th Editions - APHA Standard Methods

(i) Member, Joint Task Force for Radioactivity, APHA for the 15th, 16th, and 17th Editions - APHA Standard Methods

Publications
and Presentations

Over 100 publications and presentations in the field of radiological health. These were presented at International, national and local meetings. Papers were published in internationally and nationally recognized journals.

Special Courses

[illegible] Radiological Health
[illegible]er Programming
[illegible]damentals of Laser Protection
Executive Management Seminar

Professional Qualifications in Radiation Measurement, Protection, and Safety

Richard E. Needham
US Food & Drug Administration
US Customhouse, 2nd and Chestnut Streets
Philadelphia, PA 19106

I. Education

Master of Science, Radiopharmaceutical Science
Northeastern University, Boston, MA. (1979)

Master of Science, Nuclear Chemistry
Yale University, New Haven, CT. (1973)

Bachelor of Arts, Chemistry
Oberlin College, Oberlin, Ohio (1967)

II. Professional Experience

1985-present: Supervisory Chemist
U.S. Food and Drug Administration
Philadelphia, PA.

Duties include general supervision of an analytical chemistry laboratory of 9 chemists and one laboratory worker. Analyses performed in laboratory include products, such as in-vitro diagnostics, with radiolabelled ligands. Included in duties are the responsibilities of the facility Radiation Safety Officer.

1973-1985: Analytical Chemist
Radionuclides Section
U.S. Food and Drug Administration
Winchester, MA.

Principle duties included regulatory analysis of radiopharmaceutical diagnostic products labelled with a variety of radionuclides such as 99m-Tc, 111-In, 67-Ga, 201-Tl, 81m-Kr, 32-P. Analyses performed for radioactivity, radionuclidic purity, radiochemical purity, and biological distribution.

Performed research on detection of 129-Iodine in environmental samples by beta-gamma coincidence spectroscopy; design of a Cd(Te)-based HPLC detector for radiopharmaceuticals; influence of colloid size on biodistribution of 99m-Tc Sulfur Colloid in mice.

Responsible for maintenance and QC of a Ge(Li) and intrinsic Ge gamma ray spectroscopy system, and participated for approximately eight years in NBS National Cross-Check Program for analysis of radiopharmaceuticals.

Familiar with the maintenance and use of ionization chambers, proportional counters, liquid scintillation counters, solid-state gamma ray and alpha particle spectrometers. Also proficient in the use of a variety of dosimetry and monitoring instruments.

Acted as a technical consultant on approximately 12 FDA inspections of radiopharmaceutical manufacturers over a period of eight years.

Professional Qualifications in Radiation Measurement, Protection, and Safety

Richard E. Needham

III. Academic Coursework and Training in Radiation Measurement, Protection, and Safety

A. Academic Coursework: Northeastern University, 1974-1979

Course Title (all graduate level)	Quarter Hours Credit Earned
1. Radiation Biology & Physics	2.0
2. Nuclear Medicine	8.0 (4.0 Q.H. laboratory)
3. Dosimetry and Health Physics	2.0
4. Special Topics in Radiopharmaceuticals	2.0
5. Seminar in Radiopharmaceuticals	2.0
6. Radiopharmacy Internship	2.0

B. Academic Coursework: Yale University, 1967-1968 and 1971-1973

Course Title (all graduate level)	Semester Hours Credit Earned
1. Nuclear Chemistry	3.0
2. Introduction to Nuclear Structure	Audit
3. Nuclear Reactions and Models	Audit
4. Research (Nuclear Structure of 156 Ho)	60.0

C. Other Training Courses

1. Basic Concepts of Nuclear/Radiological Sciences and Protection
   Lowell University, Lowell, MA., 1974. Instructor: Professor Kenneth Scrable (40 hours)

2. Principles of Nuclear Medicine
   Massachusetts Institute of Technology
   Cambridge, MA. (Summer Program), 1976. Instructors: MIT Faculty (40 hours)

3. Effects on Humans of Exposure to Low Levels of Ionizing Radiation
   Yale University, New Haven, CT., 1981. Instructors: Yale University School of Medicine Faculty (5 hours)

4. Traceability of Ionizing Radiation Measurements
   National Bureau of Standards, Gaithersburg, MD., 1982.
   Instructors: NBS Staff (20 hours)

IV. Membership in Professional and Honorary Societies

1. Sigma Xi Scientific Honorary Society, nominated June, 1967
2. Rho Chi Pharmacy Honorary Society, nominated June, 1979
3. Health Physics Society, member 1977-1986
4. American Chemical Society, member 1982-present
5. American Assn. for the Advancement of Science, member 1985-present

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8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Statements of Training and Experience for four FDA Philadelphia District Laboratory Employees who will use the radionuclides specified in this application follow

JOHN MIETZ

Item 8

John L. Mietz, Supervisory Chemist
U.S. Food & Drug Administration, Philadelphia District Laboratory

Experience

Worked on a day to day basis with several tritium GLC detectors, 1963-1970

Trained by experienced FDA analysts in the T^3 foil maintenance and replacement procedures. This included disassembly and cleaning of T^3 cells and replacing the T^3 foils when necessary, 1964/1965

Radiation training included as a part of the FDA advanced analytical course at Georgetown, 1965

Performed periodic (2 x yearly) SWIPE tests on the two districts Ni^{63} GLC detectors, this included performing the Swipe, making arrangements for its testing and maintaining records of the tests, 1970

Attend approximately 1/2 day radiation safety course conducted by the Regional Radiation Safety Officer, 1980

ADA BELLO

Item 8

Ada C. Bello, Chemist
U.S. Food & Drug Administration, Philadelphia District Laboratory

Experience

University of Pennsylvania, Department of Ophthalmology, 7/69 - 6/78

Structural Studies of the Rhodopsin molecule utilizing ^{14}C-iodoacetamide for labeling the light reactive sulfhydryl group. This project included some personnel training.

Member of the Safety Committee of the Presbyt[illegible]y of Pennsylvania Medical Center, 7/76 - 6/78

University of Pennsylvania, Biochemistry [illegible] of Dental Medicine, 1/79 - 4/80

Kinetic studies of the Methylati[illegible]tRNAs [illegible] using S-adenosyl-[methyl-^{14}C]-methionir

Training

Radiochemistry - Course taken at St. Joseph's University under Dr. Grafton D. Chase, 1966

Master Thesis - Dr. Grafton D. Chase, Advisor - Research on the Metabolic Pathways of Bruised Fruit Tissue Employing Radioactive Substrates (2-^{14}C Sodium acetate and 1,5-^{14}C Citric Acid)

RITA K. JHANGIANI

Item 8

Rita K. Jhangiani, Chemist
U.S. Food & Drug Administration, Philadelphia District Laboratory

Experience

Ms. Jhangiani has worked primarily with tritium I-125 and CO-57 tagged compounds for the last thirteen years. She has developed radioimmunoassays for digoxin diethylstilbestrol and 17B-estradiol in consultation with Dr. John O'Rangers, EDPO/FDA, and Dr. Grafton Chase, FDA Science Advisor, Chemistry Department Chairman of the Philadelphia College of Pharmacy and Science, and co-author of a text book on Radioactivity and Radiochemistry techniques.

Training

1. Course at Philadelphia College of Pharmacy and Science, Radioactivity and Radioimmunoassay Techniques, 1974

2. Radioassay Techniques - The Endocrine Society Sixth Postgraduate Training Course on Radioassay Techniques, Bethesda, Maryland (one week), 1977

Job Related Experience:

During the administration of her duties and research, she has worked with 3H-DES, 3H-Estradiol (17B), ^{125}I-digoxin, ^{3}H-digoxin and ^{57}CO-B12 having a maximum specific activity of 100 Ci/mM each. No more than a total of 2 mCi of each has been in the laboratory at any one time during the past thirteen years. She has monitored the purity of the tagged isotopes by TLC and HPLC techniques. She currently is in charge of the Packard Auto-Gamma 5650 and Tri-Carb 4530 and has developed a quality control calibration program for the instruments.

In addition, she has published a literature review article on Radioimmunoassay in association with Dr. Grafton D. Chase which includes the measurement procedures for Radioimmunoassay.

ANNA LAZAR

Item 8

Anna Lazar, Chemist
U.S. Food & Drug Administration, Philadelphia District Laboratory

Experience

Stanford University Medical School, Stanford, California, 1962-63

Research Project involving ^{14}C, ^{3}H and ^{32}P labeled compounds, separation of cholesterol from complex mixtures using tracer studies

FDA, Philadelphia District Laboratory - 1974 to Present

1. Development of radioimmunoassay for diethylstilbestrol (tritium label)
2. Thyroid hormone measurements in thyroglobulin using RIA (iodine 125 and cobalt 57 label)
3. Batch certification of CEA antibody (^{125}I label)
4. Check analysis of 17B-estradiol in vitamin capsules using RIA (tritium label)
5. Immunoreactive insulin measurement in Pharmaceutical Preparation using RIA (^{125}I label)
6. Digoxin RIA (^{125}I label)
7. B-hCG determination in different materials using RIA (^{125}I label)

Training

On the job training by Dr. R. Gordon Gould, Associate Professor of Biochemistry at Stanford University.

Courses attended:

1. "Radiation Protection" DHEW/FDA, 1971
2. "Concepts of Radiation Measurement"
3. "Technology and Techniques of Radioimmunoassay" - Philadelphia College of Pharmacy and Science, 1974

Maximum radioactivity in laboratory - 100 mC

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9. FACILITIES AND EQUIPMENT

A. FACILITIES WHERE RADIONUCLIDES WILL BE USED

All operations involving radioactive material will be performed in newly renovated laboratory space on the 11th floor, US Customhouse, 2nd and Chestnut Streets, Philadelphia Pa. A floor plan of this area is included as Attachment A to this section.

Laboratory space previously used on the 12th and 13th floors of the building were vacated in March, 1988 when the 11th floor space became operational. The 11th and 12th floor radiation handling areas (fume hoods, lab benches) have been monitored for contamination using a survey meter with a NaI(Tl) gamma scintillation probe. Counting of swipes in a shielded gamma counter set for 125-I was also performed, and no levels above background were recorded.

The renovated area, portions of which are planned to be used for radioactive material handling, contains the following features of note:

1. Access to the laboratory area is controlled by a resettable combination lock installed at the main entrance door.

2. Access to the three inner laboratory rooms (Rooms 1, 2, and 3 on Attachment A), where all operations involving radionuclides will be performed, is controlled by key locks in each door entrance to these rooms.

3. For safety, each inner room contains a large window area facing both the outer laboratory space (Room 5) and the adjacent rooms, so that a full view of occupants is available throughout the laboratory area.

4. Unoccupied roof space lies directly above the laboratory, which itself forms a protruding wing of the building. Perimeter walls, with the exception of the hallway entrance area, are exterior-facing. A half-floor utility "loft" is directly below the laboratory, and also constitutes non-occupied space. Therefore, there are no potentially occupied areas directly adjacent to areas where operations will be performed in any direction.

5. Floors and ceilings are composed of reinforced concrete, approximately 10 inches thick. Floor coverings consist of seamless, non-porous material. Interior surfaces of the exterior (perimeter) walls are of glazed ceramic brick, and partition walls are gypsum board painted with gloss enamel. Doors, doorways, and trim are metal with a baked enamel finish.

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9. FACILITIES AND EQUIPMENT

A. FACILITIES WHERE RADIONUCLIDES WILL BE USED (continued)

6. Fume Hood A in Room 3 is where all work involving unsealed radioactive material will be performed. This is a Fisher Safety Fume Hood with an all stainless-steel interior and a 27" x 60" interior work surface. The exhaust stack contains an in-line activated charcoal filter for trapping of volatile radionuclides such as iodine isotopes. Exhaust capacity is 1800 cfm and average face velocity is 110 fpm for the entire face area. The hood is fitted with a manually activated washdown system which sprays the interior exhaust surfaces with water. Water, compressed air, and vacuum are supplied. Drains are directly to building sewer lines.

All operations which involve dilution, aliquotting, chemical reactions, or otherwise involve open containers containing radionuclides will be performed inside Hood A.

7. Hood B is a Labconco Biohazard Laminar Flow Hood, with a 24"x48" interior work surface, an all stainless-steel interior, and is supplied with HEPA-filtered laminar flow air. This hood, designed for microbiological use, will be used with sealed sources only.

8. Hoods C and D are Fisher Safety Fume Hoods with 27"x60" interior worksurfaces constructed of a hard, non-absorbent ceramic. Hood C will be used with sealed sources only and Hood D, located in the outer laboratory area will not be used for work with any radioactive materials except with the prior approval of the on-site Radiation Safety Officer.

8. Air supply and exhaust systems to Rooms 1,2, and 3 are set to give a slight negative pressure to minimize the potential of spread of radioactive gaseous effluents or aerosols.

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9. FACILITIES AND EQUIPMENT

B. FACILITIES FOR STORAGE OF RADIONUCLIDES

1. General storage

All radioactive sources will be labeled with a sticker label featuring a radiation caution symbol and warning as specified in 10CFR 20.203 and will be labelled as to isotope, date stored, and activity (Bequerels or equivalent) on that date.

Any source which measures greater than 10 times background at the surface with a radioactivity monitor will, before storage, be placed in a lead (or other suitable material) shield, sufficient to reduce the exposure to less than 10 times background, and labelled with the same information as the immediate container.

Sources which do not require special environmental conditions for storage will be kept in a key-locked cabinet, enameled metal on all sides, 35" wide x 19" deep x 21" high, which forms the base of Fume Hood A.

Containers will be stored on a non-porous tray with a raised edges on all four sides to minimize contamination spread if spilled. The cabinet door is permanently and prominently labeled with a radiation caution symbol and wording as specified in 10CFR 20.203.

2. Refrigerated Storage

Radionuclides requiring refrigerated storage, such as labeled biochemicals, will be stored in one of four dedicated storage areas, within the renovated laboratory space.

Refrigerated storage units are permanently and prominently labeled with a radiation caution symbol and wording as specified in 10CFR 20.203. Specific refrigerated storage facilities are as follows (refer to Attachment A):

1,2. Two household type refrigerator/freezer units are used for those products requiring short-term cold or frozen storage up to one month.

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9. FACILITIES AND EQUIPMENT

B. FACILITIES FOR STORAGE OF RADIONUCLIDES (continued)

3. A Forma Scientific walk-in refrigeration unit is used for short-term storage of radiolabeled products and in-process work requiring cold-room environmental conditions. This unit incorporates a 5'2" wide x 7'1" deep x 7'1" high work space with a 24" x 60" laminated non-porous lab bench. A condensate drain empties directly to the sewer, and a 15 cfm exhaust blower vents directly to the outside. Unsealed sources will be used in this area only with the written authorization of the on-site RSO.

4. A Revco ultra-low temperature freezer is used for radiolabeled products requiring prolonged storage at approximately -80 degrees C.

C. RADIOACTIVITY MEASUREMENT AND MONITORING EQUIPMENT

1. The following instruments will be used primarily for analytical measurements of radioactive materials, in the course of research and regulatory analysis. They will also be used as needed for monitoring areas for contamination (for example, counting of removable surface contamination)

a. Searle Mark II Liquid Scintillation Counter

This dual-channel instrument incorporates an automatic sample changer with a capacity of 300 vials, and is capable of beta-counting of 3-H, 14-C, 32-P, and 35-S in a variety of counting modes. Both manual and automatic windows settings are supported. 125-I X-rays are also detected with this instrument. Counting efficiencies for unquenched 3-H and 14-C are 60% and 95% respectively. An internal 226-Ra sealed source allows for automatic quench correction.

Quality Assurance procedures, carried out when the instrument is in use, include internal elctronic checks, counting efficiency with 3-H and 14-C, background count rate in the 3-H and 14-C windows, and a chi-squared statistical test for count reproducibility.

These performance checks are documented in an instrument logbook, along with service and repair records.

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9. FACILITIES AND EQUIPMENT

C. RADIOACTIVITY MEASUREMENT AND MONITORING EQUIPMENT (continued)

b. Packard Model 4330 Liquid Scintillation Counter

This three channel counter is similar to the Searle Liquid Scintillation Counter in its specifications and quality assurance procedures. It has the capability of displaying a multichannel beta energy spectrum, and this can be an aid in identifying beta-emitting radionuclides.

c. Packard Model 5650 Gamma Counter

This single-channel instrument has an automatic sample changer and uses a shielded NaI(Tl) detector of through-hole design for X-ray and gamma ray counting. It is capable of detecting 125-I with greater than 65% counting efficiency. Peak resolution is less than 10% for the 662 KeV peak of 137-Cs.

Quality Assurance procedures, performed when the instrument is in use, include internal electronic checks, background count rate in the 137-Cs 662 KeV photopeak region, 137-Cs peak resolution, and reproducibility of count rate (chi-squared test).

These performance checks are documented in an instrument logbook, along with service and repair records.

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9. FACILITIES AND EQUIPMENT

C. RADIOACTIVITY MEASUREMENT AND MONITORING EQUIPMENT (continued) 2. The following equipment is intended for personnel and area monitoring for contamination:

a. WB Johnson and Associates Model GSM-5Survey Meter

This instrument will operate with both a thin-window GM-tube for general monitoring and a NaI(Tl) crystal probe for X-ray and gamma-ray surface monitoring with high sensitivity.

b. Thermoluminescence Dosimeters (TLD Badges)

TLD badges are supplied by the off-site RSO Edmond J. Baratta on a quarterly basis for each user listed in Item 8. TLD's are available as whole body, wrist, and finger badges.

TLD's are also supplied quarterly for area monitoring. A TLD is provided for area monitoring of rooms 1,2, and 3 of Attcahment A.

All personnel working with 32-P will wear wrist and ring badges in addition to whole body dosimeters. All other operations will be carried out with whole body dosimeters, with wrist and ring badges optional.

TLD readings are arranged by contract via the off-site RSO. Primary records of exposure are maintained by the off-site RSO, with copies provided to the obn-site RSO.

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9. FACILITIES AND EQUIPMENT C. RADIATION PROTECTION EQUIPMENT

The following equipment and disposable items will be used for radiation protection of users as required.

1. Shielding

a. A supply of lead bricks is available to fabricate temporary and semi-permanent shielding as required.

b. A 3/8" thick transparent acrylic shield, 24" wide x 18" High x 12" Deep, will be used between source and user for all operations involving 32-P. A 3/8" thick clear acrylic storage box will be used for temporary storage of 32-P sources while in use. Use of this shiewld and storage box will be optional for other radionuclides.

2. Containment

A variety of non-porous (enameled metal, fiberglass) trays with raised edges will be used for holding sources and apparatus while in use.

3. Disposable Items

Plastic-backed absorbent paper will be used to cover all work surfaces and trays. Thiswill be disposed of as radioactive waste after use.

4. Decontamination Supplies

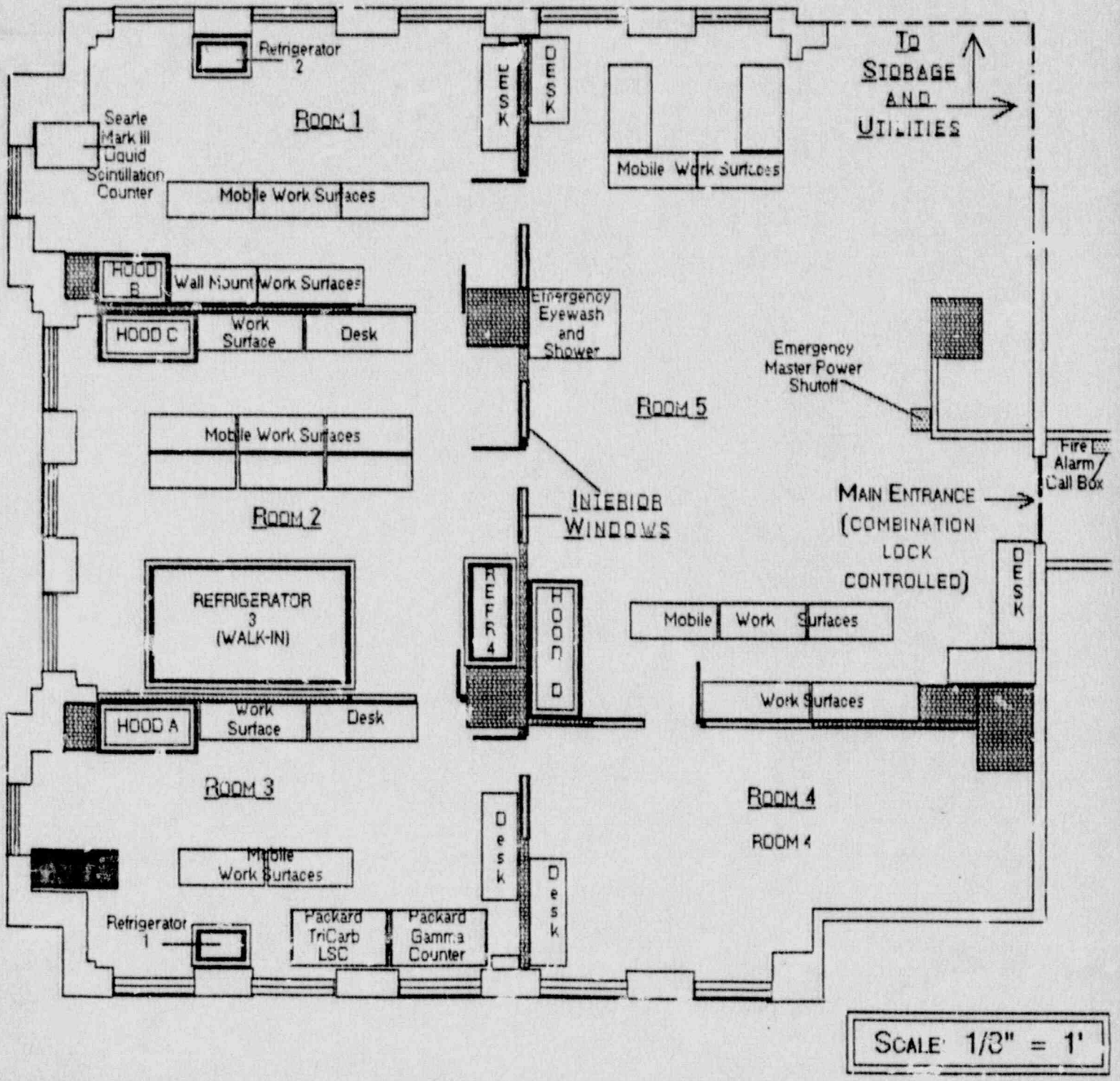
A decontamination kit, dedicated for use only in areas where radioactive materials are used, will be available. This kit consists of coveralls, shoe covers, plastic gloves, Radiacwash or similar decontamination solution, plastic bucket, sponge, mop, scrub brush, plastic bags, and radiactivity warning signs and rope.

APPLICATION FOR MATERIAL LICENSE

US FOOD AND DRUG ADMINISTRATION

PHILADELPHIA, PA 19106

9. FACILITIES AND EQUIPMENT: ATTACHMENT A



SCALE: 1/8" = 1'

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

A. ORGANIZATION

The Philadelphia District Laboratory of the Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA), Public Health Service (PHS), Department of Health and Human Services (DHHS) is located on the 11th floor of the US Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106.

Within the laboratory facilities, as described in Item 9 of this application, 3-Hydrogen, 32-Phosphorus, 35-Sulfur, and 125-Iodine will be used as tracers in research studies involving organic and biomolecules.

These radionuclides will also be used as components of commercial in-vitro diagnostic kits evaluated for FDA regulatory purposes. 63-Nickel will be used as foils and electroplated sources as components of electron-capture detectors for commercially manufactured gas chromatographs.

B. ON-SITE AND OFF-SITE RADIATION SAFETY OFFICER

Edmond J. Baratta, Radiation Safety Officer, FDA/ORA/WEAD (Winchester, MA) will serve as off-site consultant as required (Training and Experience Statement submitted as Item 7).

Richard E. Needham, Supervisory Chemist, FDA/ORA/ Philadelphia District Laboratory will serve as on-site Radiation Safety Officer (Training and Experience Statement submitted as Item 7).

C. DUTIES OF ON-SITE RADIATION SAFETY OFFICER

The duties of the on-site radiation safety officer (RSO) are:

1. To supervise the radiation monitoring of all personnel using 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, and servicing 63-Nickel Electron Capture Detectors.

2. To instruct personnel in the proper use of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, and radionuclides in general.

3. To receive, store, inspect, and record all incoming shipments of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

C. DUTIES OF RADIATION SAFETY OFFICER (continued)

4. To keep a current inventory of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

5. To supervise decontamination activities in cases of accidents or incidents involving 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides and to notify authorities as necessary and in accordance with Title 10 CFR 20.403.

6. To alter or order cessation of any operation that might result in hazardous incidents or releases to the outside environment of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides. This authority extends to cases involving releases or contamination of radioactivity and shall involve actions that are consistent with established radiation safety procedures and with the prevention of injury to employees.

7. To maintain records of personnel exposure, routine laboratory monitoring, accident reports; and to maintain records of receipt, storage, use, disposal, inspections, and transmittal of all radionuclides.

8. To maintain and calibrate survey instruments and maintain a supply of appropriate radiation protection materials, devices, and supplies.

9. To assure that all personnel follow the provisions of this Radiation Safety Program, the requirements of the Nuclear Regulatory Commission (NRC) License, and comply with Title 10 CFR Regulations.

10. To conduct a continuous program of radiation hazard evaluation and elimination, consistent with As Low as Reasonably Achievable (ALARA) principles.

11. To furnish training and assistance on all aspects of radiation protection.

12. To maintain familiarity with the current applicable NRC regulations and their application to this Radiation Safety Program.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

D. PROCUREMENT OF RADIOACTIVE MATERIALS

Requests for the procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nirkel, or other radionuclides must be submitted to the on-site RSO for approval. Procedures for the procurement of radioactive materials are as follows:

1. All requests for procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides shall be submitted to the RSO for approval. The RSO may require information on intended use and specific radiation protection protocols from the user before approving the request.

2. All incoming shipments of radionuclides shall be shipped directly to the RSO, who will prepare an inventory form (Item 10, Appendix A) before delivering the shipment to the user indicated on the request form. The inventory form shall be delivered to the user at this time.

3. It shall be the responsibility of the radionuclide user to maintain a continuous inventory of each radionuclide in the user's possession and its disposition by appropriate entries on the inventory form. Immediately upon final disposition of the radionuclide, the user shall return the form to the RSO.

4. The RSO will review the inventory form, take necessary, documented action if any inaccuracies or discrepancies are noted, and maintain the form in a manner such that it is readily retrievable for review.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS

1. A Radiation Area is defined as any area accessible to personnel in which there exists ionizing radiation, originating in whole or in part within licensed material, at such levels that a major portion of the body or critical organ could receive in one hour a dose in excess of 5 mrem, or in any five consecutive days a dose in excess of 100 mrem.

2. Each radiation area shall be conspicuously posted with a sign bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: CAUTION RADIATION AREA .

3. Each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantities listed in Title 10 CFR Part 20 Appendix C shall be designated as a Restricted Area and shall be conspicuously posted with (a) sign(s) bearing the radiation caution symbol and the words: CAUTION RADIATION AREA.

4. A room or area is not required to be posted with a caution sign in the case of the presence of a sealed source provided the radiation level at 12 inches from the surface of the source housing does not exceed 5 mrems per hour.

5. Each container in which is transported, stored, used, or contaminated with a quantity of licensed material greater than the quantity of such material specified in Title 10 CFR Part 20 Appendix C shall bear a durable, clearly visible label bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: CAUTION RADIOACTIVE MATERIAL .

6. Laboratory containers, such as beakers, flasks and test tubes used transiently in laboratory procedures, do not require individual labels while the user is present. When such containers are to be left unattended for periods of 8 hours or more and contain material in concentrations greater than those specified in Column 2, Table 1, Appendix B of Title 10 CFR Part 20, they will be labeled as described in paragraph 5 of this part.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
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10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS (continued)

7. Where containers are used for storage, the labels required by this section shall also state the quantities and kinds of radioactive materials in the containers and the units of measurement of such quantities.

8. Laboratory containers used transiently in laboratory procedures involving radionuclides will not be used outside the laboratory area designated for use of radionuclides. Reusable containers will be decontaminated and cleaned by users only in areas designated for radionuclide handling. Decontamination and cleaning shall be performed after consultation with the RSO, and shall be performed so as to minimize discharge to public drains and the outside environment.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION

Each individual who is designated as a user of, or who has contact with, any radioactive material is responsible for:

1. Keeping radiation exposure to self and coworkers as low as possible and, specifically below the Maximum Permissible Exposures listed in Appendix C of this section.

2. Wearing the prescribed personnel monitoring equipment in radiation areas.

3. Performing all operations on radioactive sources only in designated radiation handling areas as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

4. Each individual shall utilize all appropriate radiation protective measures including the following:

a. Shall wear protective outer clothing when using radionuclides.

b. Shall wear gloves and, where appropriate, respiratory protection devices as prescribed.

c. Shall use a pipette filling device and never pipette by mouth.

d. Shall perform operations on unsealed sources within the confines of a fume exhaust hood designated for this purpose, as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

5. Each user shall survey his/her hands, shoes and body for contamination using an appropriate survey meter before leaving radiation areas.

6. Smoking and eating in areas where radioactive materials are present is expressly prohibited.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION (continued)

7. Each user shall maintain good personal hygiene, to include:

a. Should keep fingernails short and clean.

b. Shall not work with radioactive materials if there is a break in the skin below the wrist.

c. Shall wash hands and arms thoroughly before leaving a radiation area.

8. Shall survey the immediate areas of fume hoods, benches, and other susceptible areas during and immediately after conclusion of the use of radioactive materials. Indicated areas of contamination should be decontaminated immediately. If such removal is not possible, the area shall be clearly marked and the RSO notified immediately.

9. Shall keep all areas where radioactive materials are used clean and orderly. The work area should be freed of equipment and materials not required for the immediate procedure.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
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10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION (continued)

10. Shall store and transport materials in appropriate containers, preferably double-barrier containers, to prevent breakage or spillage and to ensure adequate radiation shielding.

11. Shall keep work surfaces covered with absorbent material and shall employ trays or pans with raised rims and constructed of non-absorbent materials to limit and contain accidental spillage.

12. Shall label and isolate radioactive waste and equipment, such as glassware, used with radioactive materials. Equipment and conatiners used with radioactive materials shall not be used for other purposes or be removed from the radiation area for any purpose (including cleaning, repair, and surplus) unless demonstrated to be free of contamination with radioactivity.

13. Shall report all accidental releases, inhalation, ingestion, or injury involving radioactive materials to the immediate supervisor and the RSO. Individuals shall cooperate in any and all attempts to evaluate exposure and shall carry out corrective measures recommended by the RSO.

14 Refrigerators and other areas designated for storage of radioactive materials (areas described in Item 9 of this application) shall not be used for storage of food or other items that may lead to contamination of personnel.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

G. EMERGENCY PROCEDURES

Emergencies include such events as major spills of radioactive materials, fires, and explosions, by which radioactive materials may be released or dispersed. In case of emergency, the following procedures will be followed:

1. In the event of an emergency, such as fire, explosion, major spills of radioactive materials or hazardous malfunction of equipment, all persons in the radiation area shall evacuate the area immediately.

2. If warranted pull the fire alarm box, located immediately outside the door of the laboratory (see Appendix A of Item 9 of this application) where radiactive materials are used.

3. Notify the on-site RSO and immediate supervisor and follow instructions received. RSO Officer telephone: (215) 597-2123 (office); (215) 254-0091 (home).

4. If a radiological hazard is not imminent, attempts to extinguish fires are permitted.

5. Shut off heating and air-conditioning equipment, shut off exhaust fans and lower sashes in fume hoods if feasible. An emergency shutdown button for all electrical service to the laboratory area is prominently located and marked inside the entrance doors to the laboratory.

6. Monitor all persons potentially exposed to radioactivity in the area for contamination and control their movement if necessary. Summon medical help, preferably through your supervisor or the RSO, if warranted.

7. Following the emergency event, monitor the affected area and, in consultation with the on-site RSO, take steps necessary for safe and effective removal of contamination.

8. The responsible employee's supervisor shall prepare an account of the emergency situation for review by the RSO, in addition to any other reports required by district SOP and other health and safety regulations.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES

1. General Principles

Successful decontamination calls for planned actions. A hasty action or attempt at decontamination can cause more harm than good. The person responsible for a spill in a contamination accident will generally take the first steps in bringing the situation under control. Those persons responsible for a spill shall, unless physically unable, be responsible for all decontamination of the area, under the direction or supervision of the on-site RSO. The first consideration will be personnel safety; persons not involved in the spill will leave the area to a second area to be checked for possible contamination. Subsequent actions will involve the following procedures:

a. Prevention of the spread of contamination by shutting down ventilation fans, applying absorbent material in the case of liquids, and roping off or barricading the area.

b. Immediate notification of the immediate supervisor and the on-site RSO.

c. Allowing no one to leave the adjacent area or facility until the person has been checked for contamination.

c. Making full use of radiation monitoring instruments and available assistance. Each step of the decontamination process will be monitored with appropriate instruments. One person should remain uncontaminated to operate monitoring instruments. Protective footwear, gloves, and respiratory equipment shall be used as needed.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES (continued)

2. General Procedures for Decontamination of Personnel

a. Ordinarily, the same procedures used for personnel cleanliness will be sufficient to remove radioactive contaminants from the skin. Soap and water (sequestering agents and detergents) normally will remove greater than 99% of conatminants. If it is necessary to remove the remainder, agents containing chemicals such as citric acid, potassium permangenate, and sodium bisulfate can be used on the outer layers of skin where contamination remains. These agents will be applied with caution, if possible under medical supervision.

b. Remove any clothing or equipment found to be contaminated before determining levels of personal contamination.

c. Decontaminate first any areas of the body found to be significantly more contaminated than surrounding areas. This spot-cleaning approach is necessary to prevent the spread of existing contamination that might occur, for example, in showering.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION (continued)

d. If the contamination is general over the entire body, a thorough shower is necessary. Special attention will be paid to such areas as the hair, hands, and fingernails. After showering and monitoring, residual contamination can be removed by spot-cleaning.

e. Avoid the prolonged use of any one type of decontamination procedure: the effect may be to irritate and abrade the skin and thus render ineffective more suitable procedures.

f. Avoid the use of organic solvents, which may increase the penetrability of radionuclides through the outer skin layers.

g. Oxalic acid, which is a known toxin, will not be used under any circumstances for personnel decontamination.

h. Specific Procedures for Hand Decontamination:

1. Wash the skin thoroughly with a mildly abrasive soap (such as Lava soap) and water paying special attention to fingernails and areas between the fingers. Repeat the procedure if monitoring reveals remaining contamination.

2. Apply a sequestrant-detergent mixture, such as 5% water, 30% laundry detergent, 65% sequestering agent (such as Calgon), and 5% Carbose. Repeat the procedure if results are encouraging.

3. Apply a sequestrant-detergent cream, rubbing thoroughly into the skin for one minute. Repeat as long as the treatment shows that contaminants are being removed.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

I. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS

Gas Chromatographic Equipment containing 63-Ni-based electron capture detectors are cleaned and tested for contamination on a semi-annual basis. Swabs utilized in the contamination test are sent to the off-site RSO Edmond J. Baratta for liquid scintillation counting.

General policies and procedures relating to radioactive materials in gas chromatographic detectors follows:

1. All radioactive foils to be used in gas chromatography cells must be shipped to the on-site RSO, or designated individual, who will maintain a file describing the type of source, identification number and location.

2. Each cell conatining radioactive material will be permanently labeled with the radiation caution symbol of 10 CFR 20 and the words:

CAUTION:RADIOACTIVE MATERIAL

The identity and activity of the radioactive material shall appear on the label.

3. The radioactive material shall not be removed from its identifying cell except for cleaning in the manner prescribed below, and shall not be transferred to other cells.

4. The following information shall be attached to each gas chromatographic instrument which contains radioactive material:

This equipment contains a radioactive source registered with the RSO as required by license from the NRC. Notify the RSO before removing the source from this location or upon any change in custodial responsibility.

5. Gas chromatography cells shall be leak tested as specified in their license and in accordance with instructions promulgated by the off-site RSO.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM (continued)

I. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS (continued)

6. All work on cells, such as cleaning and wipe testing, will be carried out in Hood A, as decribed in Item 9 of this application. Gloves shall be worn and absorbant paper shall be used during cleaning operations.

7. Liquids generated during the cleaning operation may be disposed of into the sanitary sewer with large quantities of water.

8. All gas chromatographs shall be operated below temperature limits set by the manufacturer of the detector cell.

9. Instructions for Wipe Testing of 63-Ni detectors:

a. Wipe tests will be performed at six month intervals on all detectors containing 63-Ni sources.

b. The Certificate of Inspection supplied with the detector gives the initial wipe test results. This information will be retained for inspection by the NRC. Succeeding wipe test will be performed at six month intervals. All wipe test results will be kept on file and accessible for review.

c. Use single tipped, sterile, disposable cotton swabs in 17 x 100 mm test tubes, individually wrapped (source: Curtin-Matheson Scientific, or equivalent).

d. Moisten tip of swab with solvent (methanol, acetone, or hexane).

e. Grasp the cell; rub the moistened tip of the swab over all outside surfaces of the detector and all areas immediately adjacent. Be particularly careful to include the outlet tube terminus.

f. Place the swab in a plastic case. Be careful not to touch cotton to the plastic.

g. Fill in information on inspection card certificate (Attachment 10-1).

h. Properly pack container with swab and card in a shipping conatiner. Mail by parcel post to the off-site RSO, Edmond J. Baratta, FDA, 109 Holton Street, Winchester, MA 01890.

Item 10

APPENDIX A

DHHS/PHS/FDA/ORO

PHI-DO

Inventory of Radionuclides

User _____ Quantity _____ Supplier _____

Date Received _____ Date Assayed _____ Half Life _____

	Quantity	Date	Location, Receiver & Remarks	Final Disposition
Original Balance				
Transferred				
New Balance				
Transferred				
New Balance				
Transferred				
New Balance				
Transferred				
New Balance				

RADIOISOTOPE

Item 10
Appendix B

Nickel 63 Detector
Certificate of Inspection

District: _____ NRC License No. _____

Swipe Test

Detector
Type _____
Model No. _____
Serial No. _____

Date of Swipe Test _____ By whom _____

Test Results

Date of Test _____
Amount of Contamination _____ microcuries
Next Swipe Test Required on _____
Date Reported _____ Name _____

COMMENTS – PLACE ON BACK

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

11. WASTE MANAGEMENT PROGRAM

A. Dispose of dry, solid radioactive waste and dry materials suspected of being contaminated in plastic bags labeled as to radionuclide, activity, date, and carrying the radioactivity warning statement.

B. Disposable syringes and sealed, capped vials containing residual fluids are disposed of as dry waste.

C. Contaminated syringes needles and pipettes will first be packaged or wrapped to prevent puncture accidents.

D. 32-Phosphorus, 35-Sulfur, and 125-Iodine waste shall be disposed of in a plastic bag contained in a separate, shielded waste container designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". This material will be stored for 180 days and then surveyed. When the reading is less than twice background at the surface of the container, the waste will be disposed of as conventional trash, after first removing or defacing the Radiation Caution Warning and Symbol.

E. Radioactive waste **will not** be emptied into public sewers, as by flushing down sinks, without prior consent of the RSO. All disposals into public drains will be documented by the RSO as to the radionuclide, the date, the amount of activity, and the dilution factor.

F. 3-Hydrogen and 63-Nickel waste or materials contaminated with these isotopes, will be placed in a separate, shielded waste container designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". Liquid Scintillation Vials containing tritium liquid waste shall be capped. A log of all entries of radionuclides, activity, and date will be kept. This material will be stored for a maximum of one year, and then disposed of by contract with a licensed commercial disposal firm. (GSX Services, Inc., 3527 Whiskey Bottom Road, Laurel, MD. 20707-9761 [EPA ID No. PA7470090062] is currently used for disposal all hazardous waste generated by the laboratory).

MS-16
K-4

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

August 1, 1989

License No. 37-09752-01
Docket No. 030-06213
Control No. 110089

US Nuclear Regulatory Commission, Region 1
Attn: John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406

Dear Sirs:

I apologize for the delay in responding to your correspondence of June 2, 1989. The following information is submitted for your review.

1. Henry J. Mitskas and James T. Haigh are no longer employed at this facility. They should not be included on the license as authorized users.

2. Item 10.F.6. of our application has been revised to include a prohibition of the application of cosmetics. This has been incorporated into a revised copy of our license application, submitted herewith as enclosure 1.

3. Enclosure 2 contains the closeout survey report of the 12th and 13th floor laboratories performed in March, 1988. A survey for tritium contamination has recently been conducted and results of this survey are also included in Enclosure 2.

   The tritium survey was conducted by taking filter paper wipes of 2 cm x 2 cm areas of surfaces, and counting in a liquid scintillation counter set for the tritium window. A count of an unused filter paper was used as a blank. Note that the 12th and 13th laboratory areas have remained unoccupied since March, 1988.

4. Item 11 of our application has been revised to state that 32-Phosphorus, 35-Sulfur, and 125-Iodine waste will be held for a minimum of 180 days, 900 days, and 600 days respectively (10 half-lives) before monitoring and disposal (Enclosure 1).

110089

OFFICIAL RECORD COPY ML1

AUG 02 1989

5. Material kept for decay-in-storage will be held in a storage room directly adjacent to the laboratory area shown in Attachment A of the license. A map of this room is incorporated into our revised application (Enclosure 1) as Attachment B. This room was originally used as a walk-in vault, and contains 9 1/2" thick masonry walls. It is presently used for equipment storage and is thus not routinely occupied. An area of this room, indicated on Attachment B, will be used for decay-in-storage. Waste will be contained in plastic bags labeled with isotope, date, and exposure reading at surface and individual bags placed in a polyethylene bin labeled with a radiation caution symbol and warning statement as specified in 10CFR 20.203. An inventory of contents will be maintained. As individual bags reach the end of their storage period, they will be removed, monitored, radiation symbols defaced, and disposed of in normal waste if exposure readings are less than twice background.

To facilitate review, I am enclosing 3 enclosures: Enclosure 1 (in duplicate) is a revised submission of Parts 10 and 11 incorporating changes as set forth in this letter. Enclosure 2 is the complete closeout survey report for our 12th and 13th floor laboratories. Enclosure 3 is a copy of the revised submission of Parts 10 and 11 with revisions highlighted.

If any further information is needed to complete review of our application, please contact me. I would also appreciate receiving a supply of 5 NRC Forms 3, as ours are defaced and old.

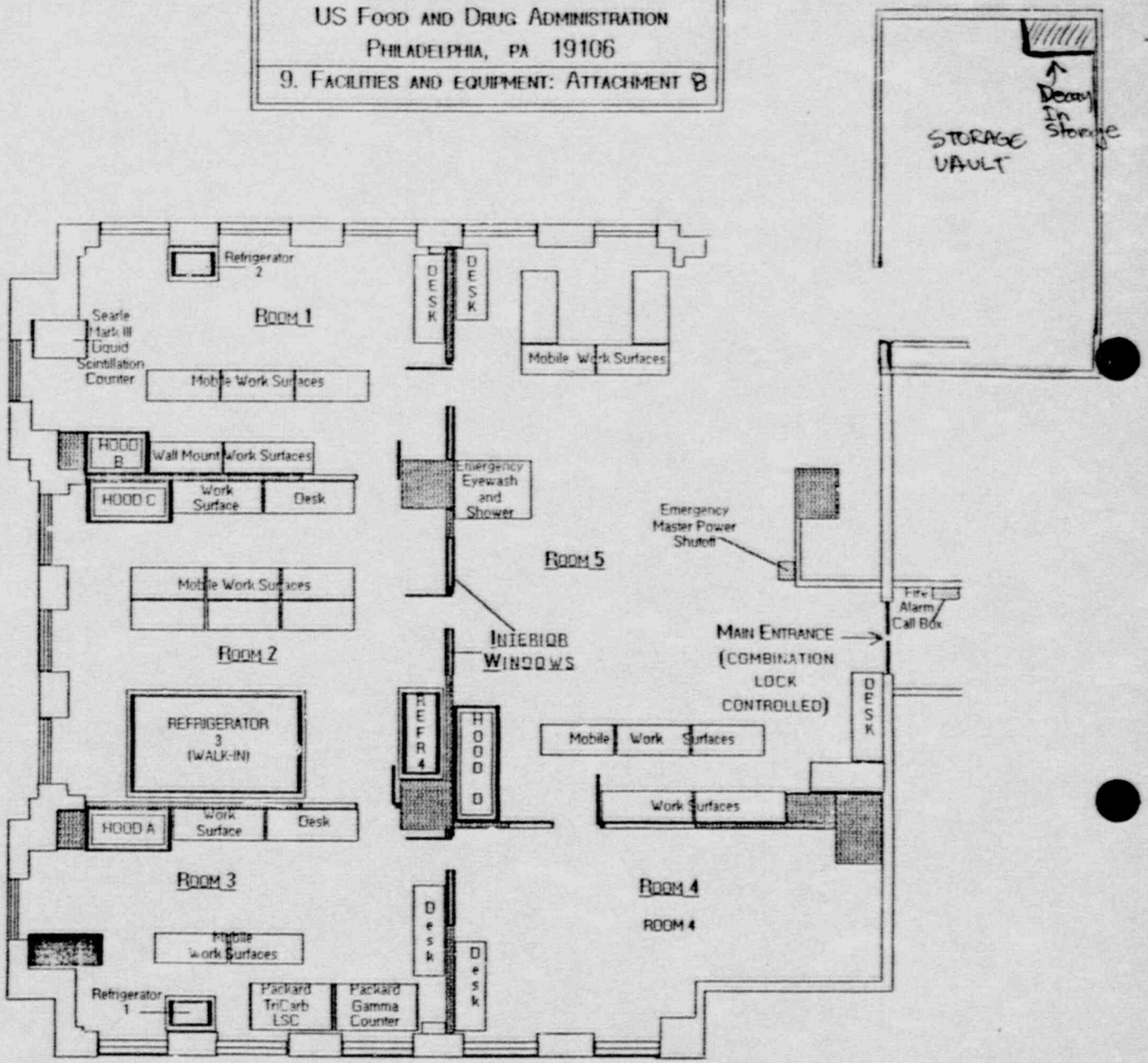
Richard E. Needham

Richard E. Needham
Supervisory Chemist

Enclosures

Enclosure 1
Control No 110089

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA 19106
9. FACILITIES AND EQUIPMENT: ATTACHMENT B



APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

A. ORGANIZATION

The Philadelphia District Laboratory of the Office of Regulatory Affairs (**ORA**), Food and Drug Administration (**FDA**), Public Health Service (**PHS**), Department of Health and Human Services (**DHHS**) is located on the 11th floor of the US Customhouse, 2nd and Chestnut Streets, Philadelphia, PA, 19106.

Within the laboratory facilities, as described in Item 9 of this application, 3-Hydrogen, 32-Phosphorus, 35-Sulfur, and 125-Iodine will be used as tracers in research studies involving organic and biomolecules.

These radionuclides will also be used as components of commercial in-vitro diagnostic kits evaluated for FDA regulatory purposes. 63-Nickel will be used as foils and electroplated sources as components of electron-capture detectors for commercially manufactured gas chromatographs.

B. ON-SITE AND OFF-SITE RADIATION SAFETY OFFICER

Edmond J. Baratta, Radiation Safety Officer, FDA/ORA/WEAC (Winchester, MA) will serve as off-site consultant as required (Training and Experience Statement submitted as Item 7).

Richard E. Needham, Supervisory Chemist, FDA/ORA/ Philadelphia District Laboratory will serve as on-site Radiation Safety Officer (Training and Experience Statement submitted as Item 7).

C. DUTIES OF ON-SITE RADIATION SAFETY OFFICER

The duties of the on-site radiation safety officer (RSO) are:

1. To supervise the radiation monitoring of all personnel using 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, and servicing 63-Nickel Electron Capture Detectors.

2. To instruct personnel in the proper use of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, and radionuclides in general.

3. To receive, store, inspect, and record all incoming shipments of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

C. DUTIES OF RADIATION SAFETY OFFICER (continued)

4. To keep a current inventory of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

5. To supervise decontamination activities in cases of accidents or incidents involving 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides and to notify authorities as necessary and in accordance with Title 10 CFR 20.403.

6. To alter or order cessation of any operation that might result in hazardous incidents or releases to the outside environment of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides. This authority extends to cases involving releases or contamination of radioactivity and shall involve actions that are consistent with established radiation safety procedures and with the prevention of injury to employees.

7. To maintain records of personnel exposure, routine laboratory monitoring, accident reports; and to maintain records of receipt, storage, use, disposal, inspections, and transmittal of all radionuclides.

8. To maintain and calibrate survey instruments and maintain a supply of appropriate radiation protection materials, devices, and supplies.

9. To assure that all personnel follow the provisions of this Radiation Safety Program, the requirements of the Nuclear Regulatory Commission (NRC) License, and comply with Title 10 CFR Regulations.

10. To conduct a continuous program of radiation hazard evaluation and elimination, consistent with **As Low as Reasonably Achievable (ALARA)** principles.

11. To furnish training and assistance on all aspects of radiation protection.

12. To maintain familiarity with the current applicable NRC regulations and their application to this Radiation Safety Program.

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10. RADIATION SAFETY PROGRAM (continued)

D. PROCUREMENT OF RADIOACTIVE MATERIALS

Requests for the procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides must be submitted to the on-site RSO for approval. Procedures for the procurement of radioactive materials are as follows:

1. All requests for procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides **shall** be submitted to the RSO for approval. The RSO may require informmation on intended use and specific radiation protection protocols from the user before approving the request.

2. All incoming shipments of radionuclides **shall** be shipped directly to the RSO, who will prepare an inventory form (**Item 10, Appendix A**) before delivering the shipment to the user indicated on the request form. The inventory form **shall** be delivered to the user at this time.

3. It **shall** be the responsibility of the radionuclide user to maintain a continuous inventory of each radionuclide in the user's possession and its disposition by appropriate entries on the inventory form. Immediately upon final disposition of the radionuclide, the user shall return the form to the RSO.

4. The RSO will review the inventory form, take necessary, documented action if any inaccuracies or discrepancies are noted, and maintain the form in a manner such that it is readily retrievable for review.

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10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS

1. A **Radiation Area** is defined as any area accessible to personnel in which there exists ionizing radiation, originating in whole or in part within licensed material, at such levels that a major portion of the body or critical organ could receive in one hour a dose in excess of 5 mrem, or in any five consecutive days a dose in excess of 100 mrem.

2. Each radiation area shall be conspicuously posted with a sign bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: **CAUTION RADIATION AREA** .

3. Each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantities listed in Title 10 CFR Part 20 Appendix C shall be designated as a **Restricted Area** and **shall** be conspicuously posted with (a) sign(s) bearing the radiation caution symbol and the words: **CAUTION RADIATION AREA.**

4. A room or area is not required to be posted with a caution sign in the case of the presence of a **sealed source** provided the radiation level at 12 inches from the surface of the source housing does not exceed 5 mrems per hour.

5. Each container in which is transported, stored, used, or contaminated with a quantity of licensed material greater than the quantity of such material specified in Title 10 CFR Part 20 Appendix C **shall** bear a durable, clearly visible label bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: **CAUTION RADIOACTIVE MATERIAL** .

6. Laboratory containers, such as beakers, flasks and test tubes used transiently in laboratory procedures, do not require individual labels while the user is present. When such containers are to be left unattended for periods of 8 hours or more and contain material in concentrations greater than those specified in Column 2, Table 1, Appendix B of Title 10 CFR Part 20, they will be labeled as described in paragraph 5 of this part.

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10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS (continued)

7. Where containers are used for storage, the labels required by this section shall also state the quantities and kinds of radioactive materials in the containers and the units of measurement of such quantities.

8. Laboratory containers used transiently in laboratory procedures involving radionuclides will not be used outside the laboratory area designated for use of radionuclides. Reusable containers will be decontaminated and cleaned by users only in areas designated for radionuclide handling. Decontamination and cleaning shall be performed after consultation with the RSO, and shall be performed so as to minimize discharge to public drains and the outside environment.

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10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION

Each individual who is designated as a user of, or who has contact with, any radioactive material is responsible for:

1. Keeping radiation exposure to self and coworkers as low as possible and, specifically below the Maximum Permissible Exposures listed in Appendix C of this section.

2. Wearing the prescribed personnel monitoring equipment in radiation areas.

3. Performing all operations on radioactive sources only in designated radiation handling areas as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

4. Each individual **shall** utilize all appropriate radiation protective measures including the following:

   a. **Shall** wear protective outer clothing when using radionuclides.

   b. **Shall** wear gloves and, where appropriate, respiratory protection devices as prescribed.

   c. **Shall** use a pipette filling device and never pipette by mouth.

   d. **Shall** perform operations on unsealed sources within the confines of a fume exhaust hood designated for this purpose, as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

5. Each user **shall** survey his/her hands, shoes and body for contamination using an appropriate survey meter before leaving radiation areas.

6. Smoking, eating, and the application of cosmetics in areas where radioactive materials are present is expressly prohibited.

7. Each user **shall** maintain good personal hygiene, to include:

   a. **Should** keep fingernails short and clean.

   b. **Shall not** work with radioactive materials if there is a break in the skin below the wrist.

   c. **Shall** wash hands and arms thoroughly before leaving a radiation area.

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10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION (continued)

8. **Shall** survey the immediate areas of fume hoods, benches, and other susceptible areas during and immediately after conclusion of the use of radioactive materials. Indicated areas of contamination should be decontaminated immediately. If such removal is not possible, the area **shall** be clearly marked and the RSO notified immediately.

9. **Shall** keep all areas where radioactive materials are used clean and orderly. The work area should be freed of equipment and materials not required for the immediate procedure.

10. **Shall** store and transport materials in appropriate containers, preferably double-barrier containers, to prevent breakage or spillage and to ensure adequate radiation shielding.

11. **Shall** keep work surfaces covered with absorbent material and **shall** employ trays or pans with raised rims and constructed of non-absorbent materials to limit and contain accidental spillage.

12. **Shall** label and isolate radioactive waste and equipment, such as glassware, used with radioactive materials. Equipment and conatiners used with radioactive materials **shall not** be used for other purposes or be removed from the radiation area for any purpose (including cleaning, repair, and surplus) unless demonstrated to be free of contamination with radioactivity.

13. **Shall** report all accidental releases, inhalation, ingestion, or injury involving radioactive materials to the immediate supervisor and the RSO. Individuals **shall** cooperate in any and all attempts to evaluate exposure and **shall** carry out corrective measures recommended by the RSO.

14. Refrigerators and other areas designated for storage of radioactive materials (areas described in Item 9 of this application) **shall not** be used for storage of food or other items that may lead to contamination of personnel.

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10. RADIATION SAFETY PROGRAM (continued)

G. EMERGENCY PROCEDURES

Emergencies include such events as major spills of radioactive materials, fires, and explosions, by which radioactive materials may be released or dispersed. In case of emergency, the following procedures will be followed:

1. In the event of an emergency, such as fire, explosion, major spills of radioactive materials or hazardous malfunction of equipment, all persons in the radiation area **shall** evacuate the area immediately.

2. If warranted, pull the fire alarm box, located immediately outside the door of the laboratory (see Appendix A of Item 9 of this application) where radiactive materials are used.

3. Notify the on-site RSO and immediate supervisor and follow instructions received. RSO Officer telephone: (215) 597-2123 (office); (215) 254-0091 (home).

4. If a radiological hazard is **not** imminent, attempts to extinguish fires are permitted.

5. Shut off heating and air-conditioning equipment, shut off exhaust fans and lower sashes in fume hoods if feasible. An emergency shutdown button for all electrical service to the laboratory area is prominently located and marked inside the entrance doors to the laboratory.

6. Monitor all persons potentially exposed to radioactivity in the area for contamination and control their movement if necessary. Summon medical help, preferably through your supervisor or the RSO, if warranted.

7. Following the emergency event, monitor the affected area and, in consultation with the on-site RSO, take steps necessary for safe and effective removal of contamination.

8. The responsible employee's supervisor **shall** prepare an account of the emergency situation for review by the RSO, in addition to any other reports required by district SOP and other health and safety regulations.

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10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES

1. General Principles

Successful decontamination calls for planned actions. A hasty action or attempt at decontamination can cause more harm than good. The person responsible for a spill in a contamination accident will generally take the first steps in bringing the situation under control. Those persons responsible for a spill shall, unless physically unable, be responsible for all decontamination of the area, under the direction or supervision of the on-site RSO. The first consideration will be personnel safety; persons not involved in the spill will leave the area to a second area to be checked for possible contamination. Subsequent actions will involve the following procedures:

a. Prevention of the spread of contamination by shutting down ventilation fans, applying absorbent material in the case of liquids, and roping off or barricading the area.

b. Immediate notification of the immediate supervisor and the on-site RSO.

c. Allowing no one to leave the adjacent area or facility until the person has been checked for contamination.

c. Making full use of radiation monitoring instruments and available assistance. Each step of the decontamination process will be monitored with appropriate instruments. One person should remain uncontaminated to operate monitoring instruments. Protective footwear, gloves, and respiratory equipment shall be used as needed.

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10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES (continued)

2. General Procedures for Decontamination of Personnel

a. Ordinarily, the same procedures used for personnel cleanliness will be sufficient to remove radioactive contaminants from the skin. Soap and water (sequestering agents and detergents) normally will remove greater than 99% of conatminants. If it is necessary to remove the remainder, agents containing chemicals such as citric acid, potassium permangenate, and sodium bisulfate can be used on the outer layers of skin where contamination remains. These agents will be applied with caution, if possible under medical supervision.

b. Remove any clothing or equipment found to be contaminated before determining levels of personal contamination.

c. Decontaminate first any areas of the body found to be significantly more contaminated than surrounding areas. This spot-cleaning approach is necessary to prevent the spread of existing contamination that might occur, for example, in showering.

d. If the contamination is general over the entire body, a thorough shower is necessary. Special attention will be paid to such areas as the hair, hands, and fingernails. After showering and monitoring, residual contamination can be removed by spot-cleaning.

e. Avoid the prolonged use of any one type of decontamination procedure: the effect may be to irritate and abrade the skin and thus render ineffective more suitable procedures.

f. Avoid the use of organic solvents, which may increase the penetrability of radionuclides through the outer skin layers.

g. Oxalic acid, which is a known toxin, will not be used under any circumstances for personnel decontamination.

h. Specific Procedures for Hand Decontamination:

1. Wash the skin thoroughly with a mildly abrasive soap and water, paying special attention to fingernails and areas between the fingers. Repeat the procedure if monitoring reveals remaining contamination.

2. Apply a sequestrant-detergent mixture, such as 5% water, 30% laundry detergent, 65% sequestering agent (such as Calgon) and 5% Carbose. Repeat the procedure if results are encouraging.

3. Apply a sequestrant-detergent cream, rubbing thoroughly into the skin for one minute. Repeat as long as the treatment shows that contaminants are being removed.

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10. RADIATION SAFETY PROGRAM (continued)

I. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS

Gas Chromatographic Equipment containing 63-Ni-based electron capture detectors are cleaned and tested for contamination on a semi-annual basis. Swabs utilized in the contamination test are sent to the off-site RSO Edmond J. Baratta for liquid scintillation counting.

General policies and procedures relating to radioactive materials in gas chromatographic detectors follows:

1. All radioactive foils to be used in gas chromatography cells must be shipped to the on-site RSO, or designated individual, who will maintain a file describing the type of source, identification number and location.

2. Each cell containing radioactive material will be permanently labeled with the radiation caution symbol of 10 CFR 20 and the words:

CAUTION:RADIOACTIVE MATERIAL

The identity and activity of the radioactive material shall appear on the label.

3. The radioactive material shall not be removed from its identifying cell except for cleaning in the manner prescribed below, and shall not be transferred to other cells.

4. The following information shall be attached to each gas chromatographic instrument which contains radioactive material:

This equipment contains a radioactive source registered with the RSO as required by license from the NRC. Notify the RSO before removing the source from this location or upon any change in custodial responsibility.

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10. RADIATION SAFETY PROGRAM (continued)

H. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS (continued)

5. Gas chromatography cells shall be leak tested as specified in their license and in accordance with instructions promulgated by the off-site RSO.

6. All work on cells, such as cleaning and wipe testing, will be carried out in Hood A, as decribed in Item 9 of this application. Gloves shall be worn and absorbent paper shall be used during cleaning operations.

7. Liquids generated during the cleaning operation may be disposed of into the sanitary sewer with large quantities of water.

8. All gas chromatographs shall be operated below temperature limits set by the manufacturer of the detector cell.

9. Instructions for Wipe Testing of 63-Ni detectors:

a. Wipe tests will be performed at six month intervals on all detectors containing 63-Ni sources.

b. The Certificate of Inspection supplied with the detector gives the initial wipe test results. This information will be retained for inspection by the NRC. Succeeding wipe test will be performed at six month intervals. All wipe test results will be kept on file and accessible for review.

c. Use single tipped, sterile, disposable cotton swabs in 17 x 100 mm test tubes, individually wrapped (source: Curtin-Matheson Scientific, or equivalent).

d. Moisten tip of swab with solvent (methanol, acetone, or hexane).

e. Grasp the cell; rub the moistened tip of the swab over all outside surfaces of the detector and all areas immediately adjacent. Be particularly careful to include the outlet tube terminus.

f. Place the swab in a plastic case. Be careful not to touch cotton to the plastic.

g. Fill in information on inspection card certificate (Attachment 10-1).

h. Properly pack container with swab and card in a shipping conatiner. Mail by parcel post to the off-site RSO, Edmond J. Baratta, FDA, 109 Holton Street, Winchester, MA 01890.

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11. WASTE MANAGEMENT PROGRAM

A. Dispose of **dry, solid** radioactive waste and dry materials suspected of being contaminated in plastic bags labeled as to radionuclide, activity, date, and carrying the radioactivity warning statement.

B. Disposable syringes and sealed, capped vials containing residual fluids are disposed of as dry waste.

C. Contaminated syringes needles and pipettes will first be packaged or wrapped to prevent puncture accidents.

D. 32-Phosphorus, 35-Sulfur, and 125-Iodine waste shall be disposed of separated by radionuclide in plastic bags labeled with the radionuclide, activity level, and date. Individual bags will be consolidated in a plastic bin designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". This material will be held in the decay-in-storage area (see Part 9, Attachment B) for the following times periods (at least ten half-lives):

32-Phosphorus:	180 Days
35-Sulfur:	900 Days
125-Iodine:	600 Days

A log will be maintained of all waste held for decay-in-storage, which will indicate the radionuclide, activity level, date disposed, and the date for the end of the decay-in-storage period.

At the end of the decay-in-storage period for each bag, the bag will be surveyed at the surface with a GM-type survey meter. If the exposure reading is less than twice background at the surface of the bag, the waste will be disposed of as conventional trash, after first removing or defacing the Radiation Caution Warning and Symbol.

E. Radioactive waste **will not** be emptied into public sewers, as by flushing down sinks, without prior consent of the RSO. All disposals into public drains will be documented by the RSO as to the radionuclide, the date, the amount of activity, and the dilution factor.

F. 3-Hydrogen and 63-Nickel waste or materials contaminated with these isotopes, will be placed in a separate, shielded waste container designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". Liquid Scintillation Vials containing tritium liquid waste shall be capped. A log of all entries of

radionuclides, activity, and date will be kept. This material will be stored for a maximum of one year, and then disposed of by contract with a licensed commercial disposal firm. (GSX Services, Inc., 3527 Whiskey Bottom Road, Laurel, MD. 20707-9761 [EPA ID No. PA7470090062] is currently used for disposal all hazardous waste generated by the laboratory).

Enclosure 2 Control No. 110089

Close-Out Survey for Tritium
FDA 12th and 13th Floor Laboratories
US Customhouse, Philadelphia, Pa

I. Summary of Procedure

A Survey for removable tritium contamination in the 12th and 13th floor laboratories of the FDA's Philadelphia District Office was performed in June, 1989. These areas had been used previously for work with tritium (3-H), 14-C, and 125-I under NRC license 37-09752. The areas were vacated in March, 1988 and work with radionuclides will now be performed in renovated laboratory space on the 11th floor of the District Office.

In March, 1988, a survey had been performed using a William B Johnson & Associates Model GSM-5 Survey Meter with a NaI(Tl) Scintillator probe, and results are attached as Attachment J.

The present survey used filter paper wipes of 4 square centimeter areas of bench tops, floors, and sink areas of the laboratory areas. Thirty two wipes were taken in the 12th floor laboratory (Attachment A) and forty five wipes in the 13th floor laboratory (Attachment C).

Wipes were placed in glass liquid scintillator vials and 10 cc of Biosafe II (Research Products International, Mt. Prospect, IL) Liquid Scintillation cocktail added to each vial. Vials were counted for 10 minutes each in a Packard Model 4530 Tricarb Liquid Scintillation Counter in the tritium window (Attachments F, G).

Previous to counting the vials the counter was calibrated with unquenched standards of tritium, 14-C, and background. The instrument passed all performance criteria (Attachment E).

Gross count rates in the tritium channel were reduced to net count rates by subtracting background counts. The background count rate was determined by placing a clean filter paper in liquid scintillation cocktail and performing 10 replicate 10 minute counts (Attachment H).

The counting efficiency for tritium on filter paper was determined by pipetting identical two microliter aliquots of a weak tritium standard (less than 500 dpm/microliter) into a liquid scintillation vial and onto a piece of filter paper. The ratio of count rates for the 'filter paper geometry' to the unquenched count rate (0.276), together with the known unquenched counting efficiency for tritium from the calibration run (0.680), was used to determine that the tritium counting efficiency for the 'filter paper geometry' was 0.276 x 0.680 = 0.188 counts/disintegration. (Attachment I).

II. Summary of Results

The highest gross count rate was 1.32 times background in the 13th floor laboratory area (Attachment D) and 1.19 times background in the 12th floor laboratory (Attachment B).

For those wipes which counted more than 2 standard deviations above background, a calculation of DPM/square centimeter of removable contamination was performed by dividing the net count rate per square centimeter by the 'filter paper geometry' efficiency. By this calculation, the highest level of removable contamination in the 12th floor laboratory was 4.1 dpm/square centimeter and on the 13th floor 7.0 dpm/square centimeter (Attachments B,D).

III. Evaluation

Results of this survey indicate that essentially no removable tritium of 14-Carbon contamination exists in the 12th and 13th floor laboratory areas. The highest count rates were 1.19 and 1.32 times background for the 12th and 13th floor laboratories, corresponding to a calculated 4.1 and 7.0 dpm/square centimeter of removable tritium.

A review of count rate vs. location shows no particular trend for the 12th floor laboratory area.

For the 13th floor laboratory, a review of count rate vs. location shows a trend for wipes 28-33 and 35. These are all floor wipes in a generally contiguous area (Attachment C). Wipes 3, 7, 13, and 17 are of sink, bench, and hood areas in the same area, where radioactive materials were most often used. However, levels of contamination are concluded to be below a level of concern for any future use of this area.

In conclusion, both 12th and 13th floor laboratory areas are considered at this point to be essentially free of radionuclide contamination.

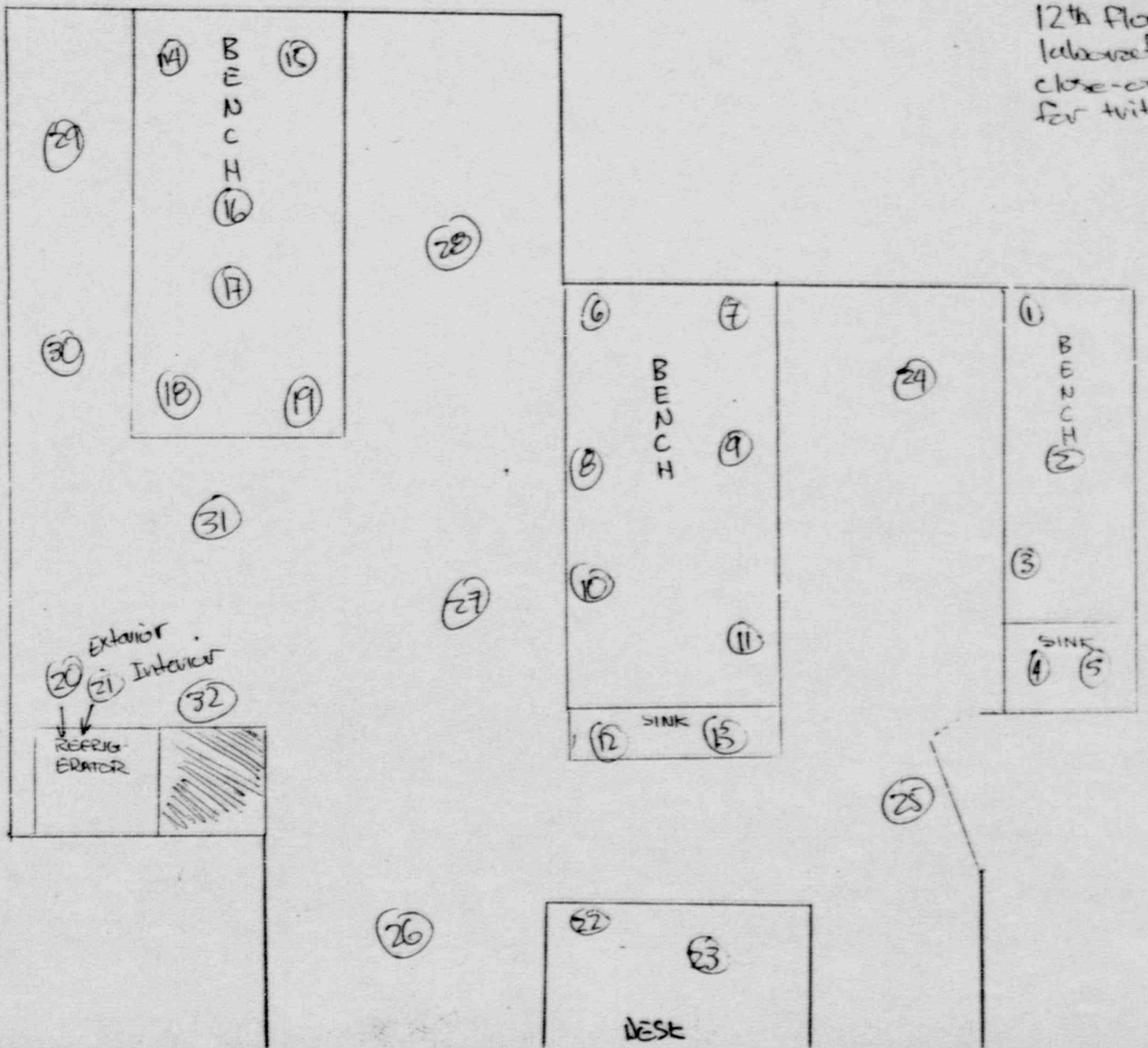
IV. List of Attachments

A. Diagram of 12th floor laboratory indicating where wipes were taken.
B. Summary of count rate and dpm/cm2 calculations for 12th floor area.
C. Diagram of 13th floor laboratory indicating where wipes were taken.
D. Summary of count rate and dpm/cm2 calculations for 13th floor area.
E. Calibration Data (14-C, 3-H, and unquenched standard counts) for Packard Tricarb Liquid Scintillation Counter.
F. Instrument Output for 12th floor area wipes, annotated.
G. Instrument Output for 12th floor area wipes, annotated.
H. Background Count Data, 'Filter Paper Geometry', annotated
I. Data for Calculation of Tritium Counting Effciency, 'Filter Paper Geometry'
J. NaI(Tl) Scintillation Probe Survey Results

Special Laboratory

Scale: 3/8" = 1 foot

12th floor laboratory close-out survey for tritium



Attachment A

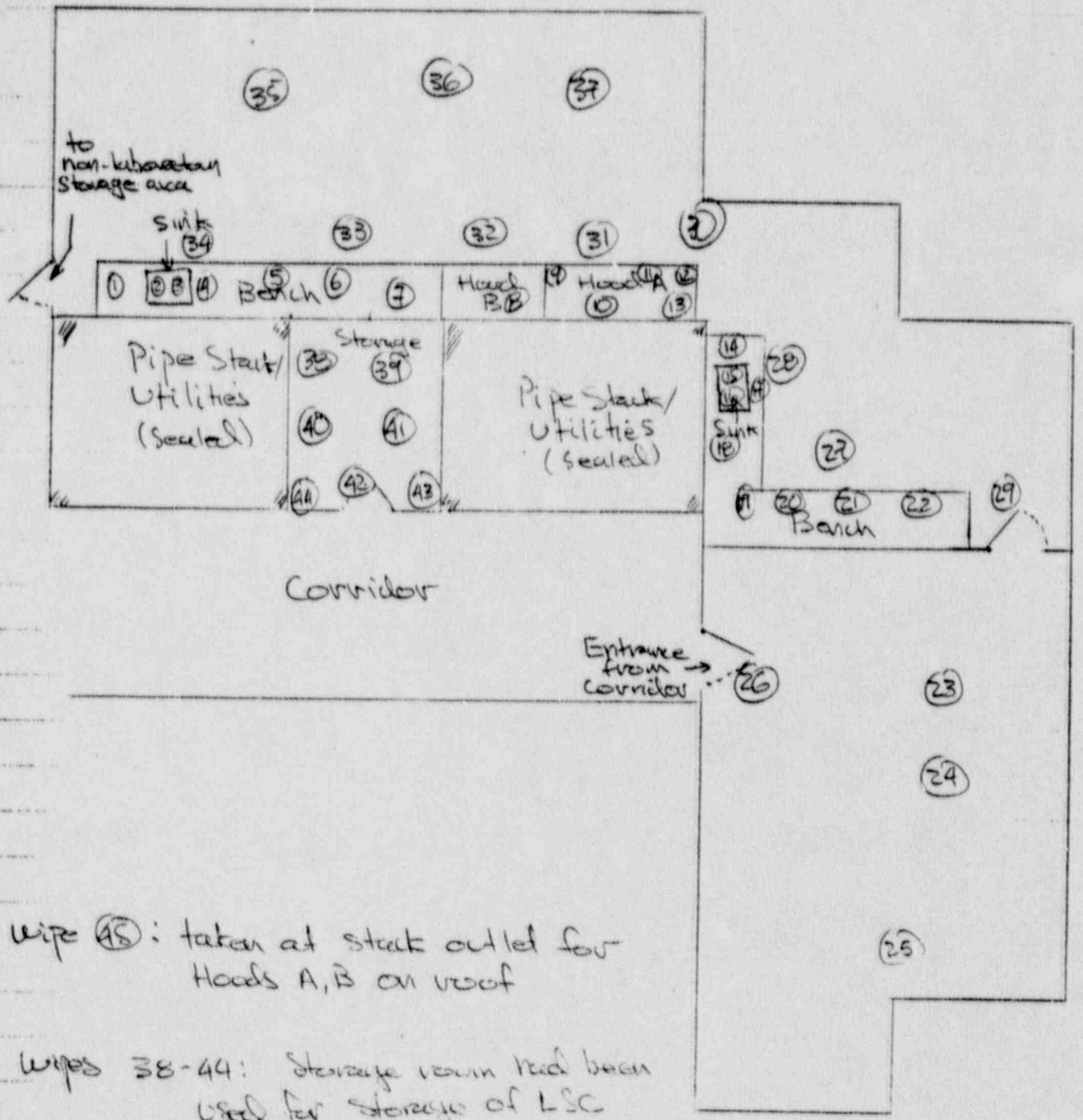
Attachment B
Close-out Survey: 12th Floor Special Laboratory
(Refer to Attacned Diagram for wipe locations)

Flag	Wipe #	CPM (Gross)	Gross/ Bkgd	CPM (Net)	DPM/cm**2 Tritium
	1	14.7	0.90	0.0	0.0
	2	15.4	0.94	0.0	0.0
	3	15.8	0.96	0.0	0.0
	4	15.0	0.91	0.0	0.0
	5	18.3	1.11	1.9	0.0
	6	14.9	0.91	0.0	0.0
	7	15.0	0.91	0.0	0.0
	8	15.8	0.96	0.0	0.0
	9	13.6	0.83	0.0	0.0
*	10	19.5	1.19	3.1	4.1
	11	14.5	0.88	0.0	0.0
	12	18.5	1.13	2.1	0.0
*	13	19.4	1.18	3.0	4.0
	14	17.7	1.08	1.3	0.0
*	15	18.6	1.13	2.2	2.9
	16	16.5	1.00	0.1	0.0
	17	17.7	1.08	1.3	0.0
	18	17.5	1.07	1.1	0.0
	19	17.3	1.05	0.9	0.0
	20	17.5	1.07	1.1	0.0
	21	15.7	0.96	0.0	0.0
	22	17.1	1.04	0.7	0.0
	23	17.0	1.04	0.6	0.0
	24	16.5	1.00	0.1	0.0
	25	13.7	0.83	0.0	0.0
*	26	18.9	1.15	2.5	3.3
	27	13.9	0.85	0.0	0.0
	28	15.3	0.93	0.0	0.0
	29	13.7	0.83	0.0	0.0
*	30	18.9	1.15	2.5	3.3
	31	15.5	0.94	0.0	0.0
	32	14.7	0.90	0.0	0.0

Background Count Rate +/- 1 sd: 16.42 +/-1.08 cpm
Flag field shows '*' if gross count is
> bkgd + 2 standard deviations

Attachment C

13th floor
Special Laboratory
Scale: 1/8" = 1 foot



Wipe 45: taken at stack outlet for Hoods A, B on roof

Wipes 38-44: Storage room had been used for storage of LSC vials after counting

Attachment D
Close-out Survey: 13th Floor Special Laboratory
(Refer to Attached Diagram for wipe locations)

Flag	Wipe #	CPM (Gross)	Gross/ Bkgd	CPM (Net)	DPM/cm**2 Tritium
	1	13.8	0.84	0.0	0.0
	2	14.1	0.86	0.0	0.0
*	3	19.5	1.19	3.1	4.1
	4	14.3	0.87	0.0	0.0
	5	18.4	1.12	2.0	0.0
	6	15.2	0.93	0.0	0.0
*	7	18.7	1.14	2.3	3.0
	8	17.7	1.08	1.3	0.0
	9	15.5	0.94	0.0	0.0
	10	16.0	0.97	0.0	0.0
	11	18.5	1.13	2.1	0.0
	12	18.5	1.13	2.1	0.0
*	13	19.5	1.19	3.1	4.1
	14	16.6	1.01	0.2	0.0
	15	16.6	1.01	0.2	0.0
	16	17.3	1.05	0.9	0.0
*	17	20.7	1.26	4.3	5.7
	18	17.4	1.06	1.0	0.0
	19	17.4	1.06	1.0	0.0
	20	17.1	1.04	0.7	0.0
	21	16.5	1.00	0.1	0.0
	22	16.7	1.02	0.3	0.0
	23	17.3	1.05	0.9	0.0
*	24	19.0	1.16	2.6	3.4
	25	18.3	1.11	1.9	0.0
	26	18.2	1.11	1.8	0.0
	27	16.9	1.03	0.5	0.0
*	28	21.7	1.32	5.3	7.0
*	29	20.9	1.27	4.5	6.0
*	30	19.3	1.18	2.9	3.8
*	31	20.3	1.24	3.9	5.2
*	32	19.9	1.21	3.5	4.6
*	33	18.7	1.14	2.3	3.0
	34	18.0	1.10	1.6	0.0
*	35	18.9	1.15	2.5	3.3
	36	14.2	0.86	0.0	0.0
	37	14.5	0.88	0.0	0.0
	38	16.2	0.99	0.0	0.0
	39	15.5	0.94	0.0	0.0
	40	15.7	0.96	0.0	0.0
	41	16.2	0.99	0.0	0.0
	42	17.8	1.08	1.4	0.0
	43	17.3	1.05	0.9	0.0
	44	15.3	0.93	0.0	0.0
	45	15.8	0.96	0.0	0.0

Background Count Rate +/- 1 sd: 16.42 +/-1.08 cpm
Flag field shows '*' if gross count is
> bkgd + 2 standard deviations

Attachment E-1

Packard Tricarb

Performance Verification

Packard background standard

PROGRAM #= 1 27/06/89 10:31

REGION A: LL-UL= 0- 19 LCR= 0 UCR= 1.00 2 σ SIGMA= .0

REGION B: LL-UL= 0- 154 LCR= 0 BKD= 1.00 2 σ SIGMA= .0

REGION C: LL-UL= 0- 0 LCR= 0 BKG= 1.00 2 σ SIGMA= .0

TIME= 10.00 I= 1.000 DIF=SIE

LUMINESCENCE CORRECTION OFF

#	S#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	1	10.00	19.20	14.4	14.90	16.3	.00	.00	1004	18.494		11
1	1	10.00	19.80	14.3	14.80	16.4	.00	.00	1002	18.403		32
1	1	10.00	20.20	13.9	14.00	16.9	.00	.00	1003	18.478		55

mean: 19.80 cpm 14.57 .00 SIE 18.458

Background standard

background count rate, quench parameter OK

(performance standard: less than 30 cpm, channel A)

background = 19.80 cpm, mean of three counts

---

quench parameter = 1009 ± 5 (SIE)

(performance standard: 1000 ± 50)

Attachment E-2
Packard Tricarb
Performance Verification
Packard Unquenched 3H Standard

PROGRAM #= 1 27/08/89 10:11
REGION A: LL=UL= 0= 12 LCR= 10 EXC= .00 % 2-SIGMA= 0
REGION B: LL=UL= 0= 12 LCR= 0 EXC= .00 % 2-SIGMA= 0
REGION C: LL=UL= 0= 0 LCR= 0 EXC= % 2-SIGMA= 0
TIME= 1.00 K= 1.000 EFF=DIE
LUMINESCENCE CORRECTION OFF

P#	S#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	1	1.00	142605.	.53	1262[illegible]	.36	.00	.00	1011	19.072	2	2
1	1	1.00	143600	.27	126057.	.35	.00	.00	999	19.090	2	2
1	1	1.00	147062.	.53	126278.	.36	.00	.00	1010	19.041	2	2
		mean:	143089.	cpm	126[illegible]4.		.00		1007	19.071		

3H unquenched standard 284500 dpm 12 Jan 84
ΔT (12 Jan 84 - 27 June 89) ≈ 5 years 5 months
From 3H decay table, Decay factor = 0.7393

% Efficiency = $\frac{143089 \text{ cpm}}{284500 \text{ dpm} \times 0.7393} \times 100 = 68.0\%$ ok

(performance standard: % efficiency ≥ 58.0%)

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Attachment E-3
Packard Tricarb Performance Verification

NORMALIZATION FACTOR 1= 774 FACTOR 2= 978

Packard unquenched 14C standard

PROGRAM #: 1 27/06/89 10:01
REGION A: LL-UL= 0- 156 LCR= 0 SCR= .00 % 2 SIGMA= .0
REGION B: LL-UL= 0- 156 LCR= 0 SCR= .00 % 2 SIGMA= .0
REGION C: LL-UL= 0- 0 LCR= 0 SCR= .00 % 2 SIGMA= .0
TIME 1.00 K= 1.000 DIP=QIE
LUMINESCENCE CORRECTION OFF

P#	S#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	PLABS	MIN
1	1	1.00	130916.	.55	126477.	.56	.00	.00	1002	161.35	1	2
1	1	1.00	130829.	.55	126496.	.56	.00	.00	1002	161.13	1	4
1	1	1.00	130861.	.55	126496.	.56	.00	.00	999	160.22	1	6
		MEAN:	130869.	CPM	126489.		.00					

14C unquenched standard 135800 dpm 15 Nov 89

% Efficiency = $\frac{130861 \text{ cpm}}{135800 \text{ dpm}} \times 100 = 96.4\%$ OK

(performance standard: % Efficiency ≥ 90.0%)

Attachment F-1

Wipe counts: 12th floor laboratory

PROGRAM #= 1 27/06/89 20:07

REGION A: LL-UL= 0- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0

REGION B: LL-UL= 2- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0

REGION C: LL-UL= 0- 0 LCR= 0 BKG= .00 % 2 SIGMA= .0

TIME= 10.00 K= 1.000 DIP=SIE

LUMINESCENCE CORRECTION OFF

P#	Wipe #	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	1	10.00	14.70	16.5	11.20	18.9	.00	.00	312.	19.437		11
1	2	10.00	15.40	16.1	12.90	17.6	.00	.00	323.	18.854		22
1	3	10.00	15.80	15.9	12.10	18.1	.00	.00	321.	20.270		33
1	4	10.00	15.00	16.3	11.40	18.7	.00	.00	337.	19.342		44
1	5	10.00	18.30	14.7	14.30	16.7	.00	.00	290.	18.786		55
1	6	10.00	14.90	16.3	11.20	18.9	.00	.00	358.	19.6[illegible]		65
1	7	10.00	15.00	16.3	12.10	18.1	.00	.00	341.	21.738		76
1	8	10.00	15.80	13.9	12.60	17.8	.00	.00	305.	19.905		87
1	9	10.00	13.60	17.1	10.00	20.0	.00	.00	339.	14.729		98
1	10	10.00	19.50	14.3	15.70	15.9	.00	.00	326.	20.738		109
1	11	10.00	14.50	16.6	10.50	19.5	.00	.00	301.	18.782		120
1	12	10.00	18.50	14.7	13.30	17.3	.00	.00	338.	17.682		131
1	13	10.00	19.40	14.3	12.70	17.7	.00	.00	339.	18.218		142
1	14	10.00	17.70	15.0	13.50	17.2	.00	.00	343.	17.583		153
1	15	10.00	18.60	14.6	13.90	16.9	.00	.00	311.	19.882		163
1	16	10.00	16.50	15.5	11.50	18.6	.00	.00	304.	19.330		174
1	17	10.00	17.70	15.0	13.90	16.9	.00	.00	341.	17.756		185
1	18	10.00	17.50	15.1	14.20	16.7	.00	.00	324.	19.883		196
1	19	10.00	17.30	15.2	13.20	17.4	.00	.00	306.	18.963		207
1	20	10.00	17.50	15.1	13.90	16.9	.00	.00	346.	18.932		218
1	21	10.00	25.80	12.4	20.90	13.8	.00	.00	571.	16.181	see next page	229
1	22	10.00	24.90	12.6	21.50	13.6	.00	.00	572.	18.358		240
1	23	10.00	25.10	12.6	20.40	14.0	.00	.00	569.	18.354		251
1	24	10.00	16.50	15.5	12.90	17.6	.00	.00	346.	19.678		262
1	25	10.00	13.70	17.0	10.50	19.5	.00	.00	290.	21.211		273
1	26	10.00	18.90	14.5	14.60	16.5	.00	.00	323.	16.370		284
1	27	10.00	13.90	16.9	10.80	19.2	.00	.00	316.	18.308		294
1	28	10.00	15.30	16.1	11.60	18.5	.00	.00	334.	17.110		305
1	29	10.00	13.70	17.0	10.80	19.2	.00	.00	308.	19.448		316
1	30	10.00	18.90	14.5	14.20	16.7	.00	.00	379.	16.573		327
1	31	10.00	15.50	16.0	11.30	18.8	.00	.00	292.	17.796		338
1	32	10.00	14.70	16.5	12.30	18.0	.00	.00	279.	19.768		349
1	33	10.00	22.20	13.4	18.10	14.8	.00	.00	532.	18.594	unusual high	
1	34	10.00	17.90	14.9	14.60	16.5	.00	.00	379.	17.507	bkgd filter paper geometry	371

Attachment F-2

Wipe counts: 12th floor laboratory

Note: Vials 21, 22, and 23 (on previous page) were inadvertently counted without wipes placed in vials and are therefore counts of unquenched background of the cocktail.

New wipes were taken and counted (21, 22, 23 below).

The last 3 counts are of a background filter paper in LSC cocktail

PROGRAM #= 1

REGION A: LL-UL= 0- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0 28/06/89 08:37

REGION B: LL-UL= 2- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0

REGION C: LL-UL= 0- 0 LCR= 0 BKG= .00 % 2 SIGMA= .0

TIME= 10.00 K= 1.000 QIP=SIE

LUMINESCENCE CORRECTION OFF

P#	Wipe #/#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
	21	10.00	15.50	16.0	11.60	18.5	.00	.00	410.	16.332		11
1	21	10.00	16.60	15.5	14.10	16.8	.00	.00	412.	19.904		22
1	21	10.00	14.90	16.3	12.00	18.2	.00	.00	413.	17.313		33
		Mean:	15.67		12.57		.00		412.	17.850		
1	22	10.00	18.00	14.9	14.30	16.7	.00	.00	323.	19.598		44
1	22	10.00	16.60	15.5	13.40	17.2	.00	.00	325.	18.971		55
	22	10.00	16.80	15.4	13.10	17.4	.00	.00	325.	18.703		65
		Mean:	17.13		13.60		.00		324.	19.091		
1	23	10.00	17.40	15.1	14.60	16.5	.00	.00	334.	19.348		76
	23	10.00	16.90	15.3	13.80	17.0	.00	.00	335.	20.009		87
1	23	10.00	16.80	15.4	13.70	17.0	.00	.00	335.	23.442		98
		Mean:	17.03		14.03		.00		335.	20.933		
	4	10.00	15.50	16.0	12.40	17.9	.00	.00	311.	20.178	bkgd filter paper geometry	109
1	4	10.00	14.30	16.7	12.30	18.0	.00	.00	312.	20.683		119
1	4	10.00	15.80	15.9	13.00	17.5	.00	.00	313.	21.097		130
			15.20		12.57		.00		312.	20.653		

Attachment G-1 : Wipe counts: 13th floor laboratory

PROGRAM #= 1 28/06/89 23:39

REGION A: LL-UL= 0- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0

REGION B: LL-UL= 2- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0

REGION C: LL-UL= 0- 0 LCR= 0 BKG= .00 % 2 SIGMA= .0

TIME= 10.00 K= 1.000 QIP=SIE

LUMINESCENCE CORRECTION OFF

P#	wipe #	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	1	10.00	13.80	17.0	10.20	19.8	.00	.00	298.	22.907		10
1	2	10.00	14.10	16.8	11.20	18.9	.00	.00	354.	19.329		21
1	3	10.00	19.50	14.3	14.90	16.3	.00	.00	356.	17.802		32
1	4	10.00	14.30	16.7	10.90	19.1	.00	.00	273.	20.735		43
1	5	10.00	18.40	14.7	14.80	16.4	.00	.00	299.	16.657		54
1	6	10.00	15.20	16.2	11.60	18.5	.00	.00	332.	21.256		65
1	7	10.00	18.70	14.6	13.20	17.4	.00	.00	322.	19.677		76
1	8	10.00	17.70	15.0	12.90	17.6	.00	.00	325.	20.162		87
1	9	10.00	15.50	16.0	11.00	19.0	.00	.00	317.	20.174		97
1	10	10.00	16.00	15.8	11.90	18.3	.00	.00	303.	19.494		108
1	11	10.00	18.50	14.7	12.00	18.2	.00	.00	301.	16.825		119
1	12	10.00	18.50	14.7	15.00	16.3	.00	.00	274.	21.637		130
1	13	10.00	19.50	14.3	13.60	17.1	.00	.00	339.	18.027		141
1	14	10.00	16.60	15.5	12.60	17.8	.00	.00	344.	18.149		152
1	15	10.00	16.60	15.5	12.90	17.6	.00	.00	354.	22.102		163
1	16	10.00	17.30	15.2	14.50	16.6	.00	.00	297.	18.018		174
1	17	10.00	20.70	13.9	11.20	18.9	.00	.00	345.	14.240		185
1	18	10.00	28.20	11.9	12.80	17.6	.00	.00	321.	13.125	1	195
1	19	10.00	17.40	15.1	12.60	17.8	.00	.00	293.	20.452		206
1	20	10.00	17.10	15.2	13.20	17.4	.00	.00	315.	18.440		217
1	21	10.00	16.50	15.5	12.60	17.8	.00	.00	327.	17.896		228
1	22	10.00	16.70	15.4	12.00	18.2	.00	.00	285.	18.249		239
1	23	10.00	17.30	15.2	12.70	17.7	.00	.00	289.	20.074		250
1	24	10.00	19.00	14.5	15.10	16.2	.00	.00	310.	20.390		261
1	25	10.00	18.30	14.7	14.90	16.3	.00	.00	341.	20.715		272
1	26	10.00	18.20	14.8	14.30	16.7	.00	.00	345.	18.585		283
1	27	10.00	16.90	15.3	11.40	18.7	.00	.00	305.	18.556		293
1	28	10.00	21.70	13.5	14.00	16.9	.00	.00	361.	14.155		304
1	29	10.00	20.90	13.8	14.30	16.7	.00	.00	335.	16.970		315
1	30	10.00	19.30	14.4	12.00	18.2	.00	.00	341.	15.875		326
1	31	10.00	20.30	14.0	14.70	16.5	.00	.00	321.	19.245		337
1	32	10.00	19.90	14.1	13.50	17.2	.00	.00	317.	18.362		348
1	33	10.00	18.70	14.6	14.10	16.8	.00	.00	281.	19.722		359
1	34	10.00	18.00	14.9	13.90	16.9	.00	.00	322.	21.101		370
1	35	10.00	18.90	14.5	14.90	16.3	.00	.00	324.	19.576		381
1	36	10.00	14.20	16.7	11.70	18.4	.00	.00	327.	20.726		391
1	37	10.00	14.50	16.6	11.10	18.9	.00	.00	275.	18.618		402
1	38	10.00	16.20	15.7	12.80	17.6	.00	.00	298.	23.356		413
1	39	10.00	15.50	16.0	12.60	17.8	.00	.00	344.	22.548		424
1	40	10.00	15.70	15.9	12.00	18.2	.00	.00	321.	20.164		435
1	41	10.00	16.20	15.7	14.10	16.8	.00	.00	279.	21.018		446
1	42	10.00	17.80	14.9	13.20	17.4	.00	.00	326.	16.766		457
1	43	10.00	17.30	15.2	12.10	18.1	.00	.00	321.	18.528		468
1	44	10.00	15.30	16.1	11.80	18.4	.00	.00	349.	19.200		479
1	45	10.00	15.80	15.9	12.90	17.6	.00	.00	308.	17.792		489

See next page

Attachment Gx-2

Note: The flags field for vial # 18 on attachment Gx-1 was set, indicating interference by residual luminescence. This vial was recounted below

PROGRAM #= 1 30 06 09:29
REGION A: LL-UL= 0- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0
REGION B: LL-UL= 2- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0
REGION C: LL-UL= 0- 0 LCR= 0 BKG= .00 % 2 SIGMA= .0
TIME= 10.00 K= 1.000 QIP=SIE
LUMINESCENCE CORRECTION OFF

P#	S#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	18	10.00	17.40	15.1	13.30	17.3	.00	.00	310.	18.957		10

Attachment H

6/29/89 - tritium survey for close-out of 12th floor laboratory

1. background count rates

Results

ct	date	time	bkgd vials (cpm)
1	6/27	[illegible]20:01	17.10
2	6/28	[illegible]02:18	17.90
3	6/28	10:[illegible]26	15.50
4	6/28	10:[illegible]36	14.30
5	6/28	10:47	15.80
6	6/28	13:27	16.20
7	6/28	13:39	15.90
8	6/28	13:50	17.80
9	6/28	14:02	17.40
10	6/28	14:18	16.80

mean =	16.42	
1 s.d. =	1.08	(15.34 - 17.50)
2 s.d. =	2.16	(14.26 - 18.58)

Attachment I
efficiency calculation: 3H in filter paper geometry

PROGRAM #= 1 28/06/89 14:27
REGION A: LL-UL= 0- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0
REGION B: LL-UL= 2- 19 LCR= 0 BKG= .00 % 2 SIGMA= .0
REGION C: LL-UL= 0- 0 LCR= 0 BKG= .00 % 2 SIGMA= .0
TIME= 5.00 F= 1.000,CIP=SIE
LUMINESCENCE CORRECTION OFF

P#	S#	TIME	CPMA/K	%DEV	CPMB/K	%DEV	CPMC/K	%DEV	SIE	SIS	FLAGS	MIN
1	1	5.00	364.20	4.69	195.80	6.39	.00	.00	587.	9.143		6
1	1	5.00	389.60	4.53	208.60	6.19	.00	.00	582.	8.979		12
1	1	5.00	394.80	4.50	222.00	6.00	.00	.00	589.	9.178		18
		mean:	382.87		208.80		.00		586.	9.100		
1	2	5.00	92.80	9.28	50.40	12.6	.00	.00	337.	10.592		24
1	2	5.00	109.40	8.55	58.60	11.6	.00	.00	335.	10.202		29
1	2	5.00	115.00	8.34	59.40	11.6	.00	.00	334.	9.763		35
		mean:	105.73		56.13		.00		335.	10.185		

sample #1: approximately 500 dpm (2 λ) of 3H labeled sulfamethazine from chromatest II reagent, directly into LSC vial and made up with cocktail

sample #2: 2 λ of same solution spotted onto filter paper and placed in LSC vial, made up with cocktail

ratio = $\frac{105.73}{382.84} = 0.276$ | Efficiency for filter paper geometry = 0.276 × 68.0% = 18.8% = 0.188 ← Attachment E-2

Attachment J

4/18/88

Survey of 12th and 13th floor laboratories for residual activity:

A. Instrument
Wm. B. Johnson + Associates Model GSM-5 Survey Meter
Probe: DGSP-2A NaI(Tl) scintillation probe @ 1200 V

B. Background Readings
350 ± 75 counts/minute

C. 12th floor laboratory + 13th floor laboratory
All desk, bench, and sink areas as indicated on the attached diagrams were surveyed by holding the end of the uncapped probe within ~ 1/8" of surfaces. After a general sweep of these areas, the probe was held for approximately 30 seconds above selected areas, as indicated by numbers on the attached diagrams.
Selected floor areas were also surveyed by holding the probe for approx. 30 seconds 1/8" above floor; areas where this was done are indicated on the attached diagrams.

D. Results
No readings exceeded the 350 ± 75 cpm background rate for all areas surveyed

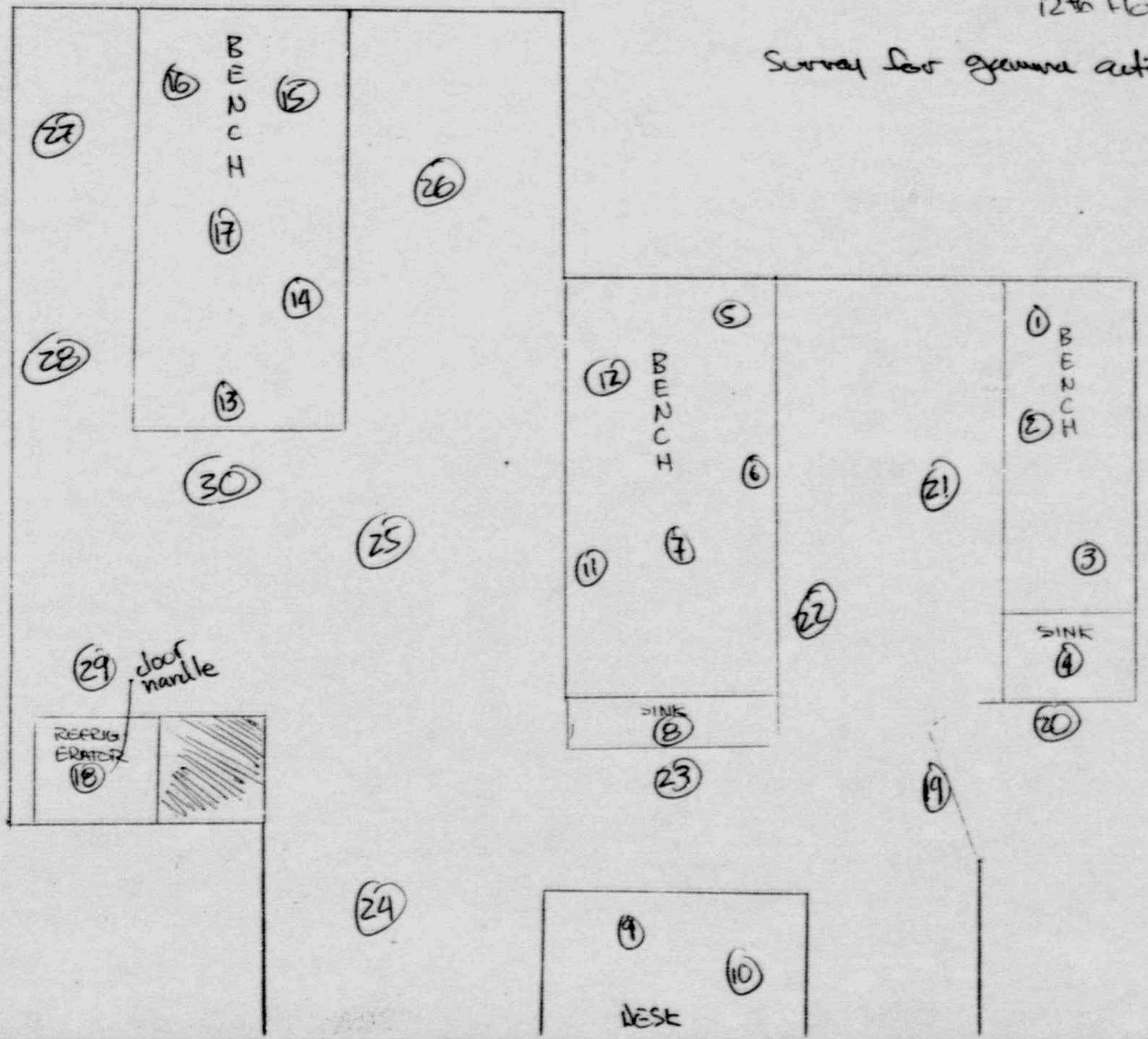
E. Conclusion
No detectable gamma-emitting radionuclide contamination in 12th, 13th floor laboratories

Special Laboratory

Scale: 3/8" = 1 foot

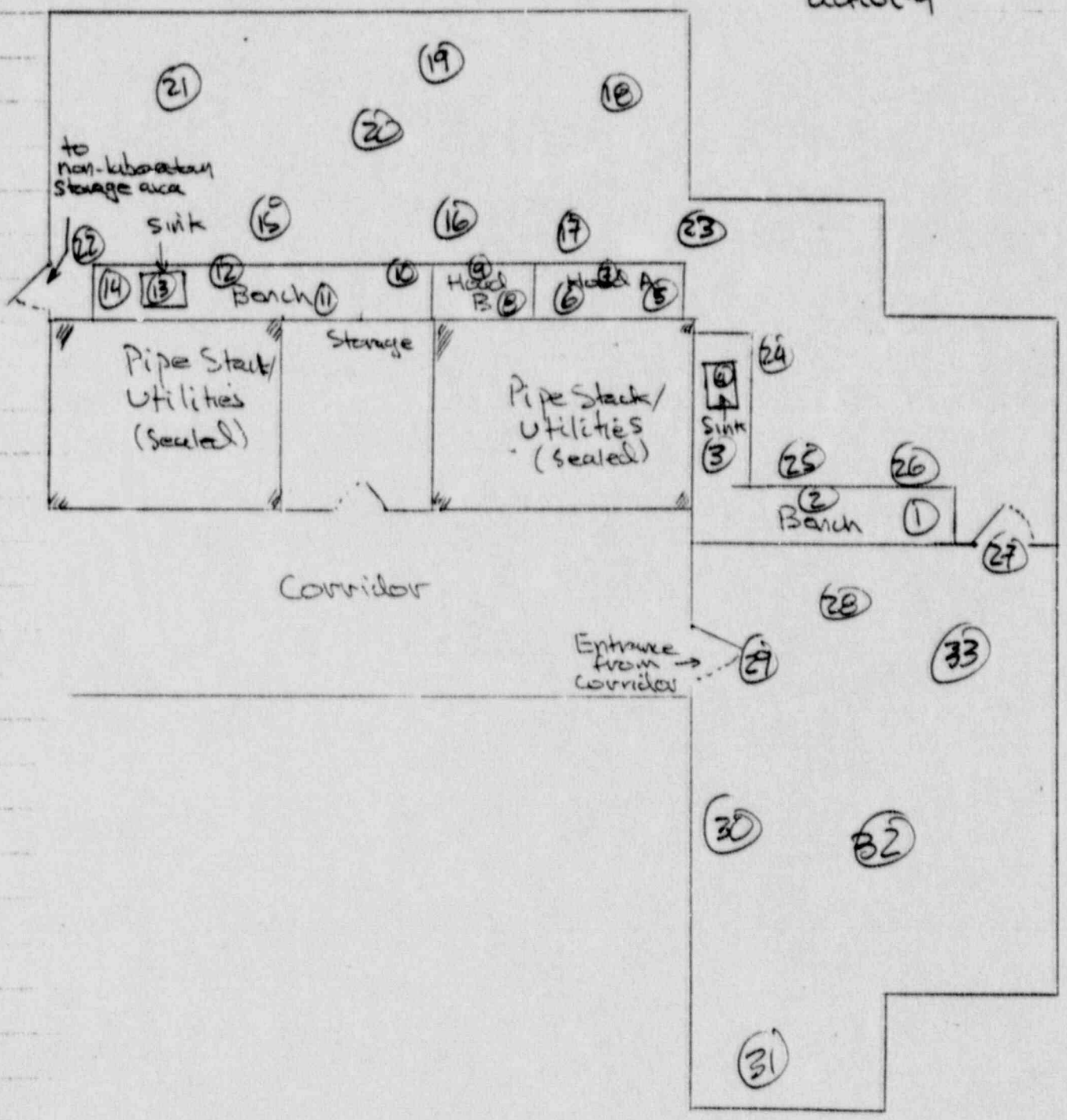
12th floor

Survey for grease activity



13th floor
Special laboratory
Scale: 1/8" = 1 foot

Survey for X activity



Enclosure 3
Control No 110089

APPLICATION FOR MATERIAL LICENSE
US FOOD AND DRUG ADMINISTRATION
PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

A. ORGANIZATION

The Philadelphia District Laboratory of the Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA), Public Health Service (PHS), Department of Health and Human Services (DHHS) is located on the 11th floor of the US Customhouse, 2nd and Chestnut Streets, Philadelphia, PA, 19106.

Within the laboratory facilities, as described in Item 9 of this application, 3-Hydrogen, 32-Phosphorus, 35-Sulfur, and 125-Iodine will be used as tracers in research studies involving organic and biomolecules.

These radionuclides will also be used as components of commercial in-vitro diagnostic kits evaluated for FDA regulatory purposes. 63-Nickel will be used as foils and electroplated sources as components of electron-capture detectors for commercially manufactured gas chromatographs.

B. ON-SITE AND OFF-SITE RADIATION SAFETY OFFICER

Edmond J. Baratta, Radiation Safety Officer, FDA/ORA/WEAC (Winchester, MA) will serve as off-site consultant as required (Training and Experience Statement submitted as Item 7).

Richard E. Needham, Supervisory Chemist, FDA/ORA/ Philadelphia District Laboratory will serve as on-site Radiation Safety Officer (Training and Experience Statement submitted as Item 7).

C. DUTIES OF ON-SITE RADIATION SAFETY OFFICER

The duties of the on-site radiation safety officer (RSO) are:

1. To supervise the radiation monitoring of all personnel using 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, and servicing 63-Nickel Electron Capture Detectors.

2. To instruct personnel in the proper use of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, and radionuclides in general.

3. To receive, store, inspect, and record all incoming shipments of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

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APPLICATION FOR MATERIAL LICENSE
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PHILADELPHIA, PA

10. RADIATION SAFETY PROGRAM

C. DUTIES OF RADIATION SAFETY OFFICER (continued)

4. To keep a current inventory of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides.

5. To supervise decontamination activities in cases of accidents or incidents involving 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides and to notify authorities as necessary and in accordance with Title 10 CFR 20.403.

6. To alter or order cessation of any operation that might result in hazardous incidents or releases to the outside environment of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides. This authority extends to cases involving releases or contamination of radioactivity and shall involve actions that are consistent with established radiation safety procedures and with the prevention of injury to employees.

7. To maintain records of personnel exposure, routine laboratory monitoring, accident reports; and to maintain records of receipt, storage, use, disposal, inspections, and transmittal of all radionuclides.

8. To maintain and calibrate survey instruments and maintain a supply of appropriate radiation protection materials, devices, and supplies.

9. To assure that all personnel follow the provisions of this Radiation Safety Program, the requirements of the Nuclear Regulatory Commission (NRC) License, and comply with Title 10 CFR Regulations.

10. To conduct a continuous program of radiation hazard evaluation and elimination, consistent with **As Low as Reasonably Achievable (ALARA)** principles.

11. To furnish training and assistance on all aspects of radiation protection.

12. To maintain familiarity with the current applicable NRC regulations and their application to this Radiation Safety Program.

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10. RADIATION SAFETY PROGRAM (continued)

D. PROCUREMENT OF RADIOACTIVE MATERIALS

Requests for the procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides must be submitted to the on-site RSO for approval. Procedures for the procurement of radioactive materials are as follows:

1. All requests for procurement of 3-Hydrogen, 32-Phosphorus, 35-Sulfur, 125-Iodine, 63-Nickel, or other radionuclides **shall** be submitted to the RSO for approval. The RSO may require informmation on intended use and specific radiation protection protocols from the user before approving the request.

2. All incoming shipments of radionuclides **shall** be shipped directly to the RSO, who will prepare an inventory form (**Item 10, Appendix A**) before delivering the shipment to the user indicated on the request form. The inventory form **shall** be delivered to the user at this time.

3. It **shall** be the responsibility of the radionuclide user to maintain a continuous inventory of each radionuclide in the user's possession and its disposition by appropriate entries on the inventory form. Immediately upon final disposition of the radionuclide, the user shall return the form to the RSO.

4. The RSO will review the inventory form, take necessary, documented action if any inaccuracies or discrepancies are noted, and maintain the form in a manner such that it is readily retrievable for review.

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10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS

1. A **Radiation Area** is defined as any area accessible to personnel in which there exists ionizing radiation, originating in whole or in part within licensed material, at such levels that a major portion of the body or critical organ could receive in one hour a dose in excess of 5 mrem, or in any five consecutive days a dose in excess of 100 mrem.

2. Each radiation area shall be conspicuously posted with a sign bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: **CAUTION RADIATION AREA** .

3. Each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantities listed in Title 10 CFR Part 20 Appendix C shall be designated as a **Restricted Area** and **shall** be conspicuously posted with (a) sign(s) bearing the radiation caution symbol and the words: **CAUTION RADIATION AREA.**

4. A room or area is not required to be posted with a caution sign in the case of the presence of a **sealed source** provided the radiation level at 12 inches from the surface of the source housing does not exceed 5 mrems per hour.

5. Each container in which is transported, stored, used, or contaminated with a quantity of licensed material greater than the quantity of such material specified in Title 10 CFR Part 20 Appendix C **shall** bear a durable, clearly visible label bearing the Radiation Caution Symbol (10 CFR 20.203[a]) and the words: **CAUTION RADIOACTIVE MATERIAL** .

6. Laboratory containers, such as beakers, flasks and test tubes used transiently in laboratory procedures, do not require individual labels while the user is present. When such containers are to be left unattended for periods of 8 hours or more and contain material in concentrations greater than those specified in Column 2, Table 1, Appendix B of Title 10 CFR Part 20, they will be labeled as described in paragraph 5 of this part.

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10. RADIATION SAFETY PROGRAM (continued)

E. RADIATION AREAS (continued)

7. Where containers are used for storage, the labels required by this section shall also state the quantities and kinds of radioactive materials in the containers and the units of measurement of such quantities.

8. Laboratory containers used transiently in laboratory procedures involving radionuclides will not be used outside the laboratory area designated for use of radionuclides. Reusable containers will be decontaminated and cleaned by users only in areas designated for radionuclide handling. Decontamination and cleaning shall be performed after consultation with the RSO, and shall be performed so as to minimize discharge to public drains and the outside environment.

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10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION

Each individual who is designated as a user of, or who has contact with, any radioactive material is responsible for:

1. Keeping radiation exposure to self and coworkers as low as possible and, specifically below the Maximum Permissible Exposures listed in Appendix C of this section.

2. Wearing the prescribed personnel monitoring equipment in radiation areas.

3. Performing all operations on radioactive sources only in designated radiation handling areas as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

4. Each individual **shall** utilize all appropriate radiation protective measures including the following:

   a. **Shall** wear protective outer clothing when using radionuclides.

   b. **Shall** wear gloves and, where appropriate, respiratory protection devices as prescribed.

   c. **Shall** use a pipette filling device and never pipette by mouth.

   d. **Shall** perform operations on unsealed sources within the confines of a fume exhaust hood designated for this purpose, as set forth in Item 9 of this application, or in other areas only with the prior approval of the on-site RSO.

5. Each user **shall** survey his/her hands, shoes and body for contamination using an appropriate survey meter before leaving radiation areas.

6. Smoking, eating, **and the application of cosmetics** in areas where radioactive materials are present is expressly prohibited.

7. Each user **shall** maintain good personal hygiene, to include:

   a. **Should** keep fingernails short and clean.

   b. **Shall not** work with radioactive materials if there is a break in the skin below the wrist.

   c. **Shall** wash hands and arms thoroughly before leaving a radiation area.

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10. RADIATION SAFETY PROGRAM (continued)

F. INDIVIDUAL RESPONSIBILITY FOR RADIATION PROTECTION (continued)

8. **Shall** survey the immediate areas of fume hoods, benches, and other susceptible areas during and immediately after conclusion of the use of radioactive materials. Indicated areas of contamination should be decontaminated immediately. If such removal is not possible, the area **shall** be clearly marked and the RSO notified immediately.

9. **Shall** keep all areas where radioactive materials are used clean and orderly. The work area should be freed of equipment and materials not required for the immediate procedure.

10. **Shall** store and transport materials in appropriate containers, preferably double-barrier containers, to prevent breakage or spillage and to ensure adequate radiation shielding.

11. **Shall** keep work surfaces covered with absorbent material and **shall** employ trays or pans with raised rims and constructed of non-absorbent materials to limit and contain accidental spillage.

12. **Shall** label and isolate radioactive waste and equipment, such as glassware, used with radioactive materials. Equipment and conatiners used with radioactive materials **shall not** be used for other purposes or be removed from the radiation area for any purpose (including cleaning, repair, and surplus) unless demonstrated to be free of contamination with radioactivity.

13. **Shall** report all accidental releases, inhalation, ingestion, or injury involving radioactive materials to the immediate supervisor and the RSO. Individuals **shall** cooperate in any and all attempts to evaluate exposure and **shall** carry out corrective measures recommended by the RSO.

14. Refrigerators and other areas designated for storage of radioactive materials (areas described in Item 9 of this application) **shall not** be used for storage of food or other items that may lead to contamination of personnel.

APPLICATION FOR MATERIAL LICENSE
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10. RADIATION SAFETY PROGRAM (continued)

G. EMERGENCY PROCEDURES

Emergencies include such events as major spills of radioactive materials, fires, and explosions, by which radioactive materials may be released or dispersed. In case of emergency, the following procedures will be followed:

1. In the event of an emergency, such as fire, explosion, major spills of radioactive materials or hazardous malfunction of equipment, all persons in the radiation area **shall** evacuate the area immediately.

2. If warranted, pull the fire alarm box, located immediately outside the door of the laboratory (see Appendix A of Item 9 of this application) where radiactive materials are used.

3. Notify the on-site RSO and immediate supervisor and follow instructions received. RSO Officer telephone: (215) 597-2123 (office); (215) 254-0091 (home).

4. If a radiological hazard is **not** imminent, attempts to extinguish fires are permitted.

5. Shut off heating and air-conditioning equipment, shut off exhaust fans and lower sashes in fume hoods if feasible. An emergency shutdown button for all electrical service to the laboratory area is prominently located and marked inside the entrance doors to the laboratory.

6. Monitor all persons potentially exposed to radioactivity in the area for contamination and control their movement if necessary. Summon medical help, preferably through your supervisor or the RSO, if warranted.

7. Following the emergency event, monitor the affected area and, in consultation with the on-site RSO, take steps necessary for safe and effective removal of contamination.

8. The responsible employee's supervisor **shall** prepare an account of the emergency situation for review by the RSO, in addition to any other reports required by district SOP and other health and safety regulations.

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10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES

1. General Principles

Successful decontamination calls for planned actions. A hasty action or attempt at decontamination can cause more harm than good. The person responsible for a spill in a contamination accident will generally take the first steps in bringing the situation under control. Those persons responsible for a spill shall, unless physically unable, be responsible for all decontamination of the area, under the direction or supervision of the on-site RSO. The first consideration will be personnel safety; persons not involved in the spill will leave the area to a second area to be checked for possible contamination. Subsequent actions will involve the following procedures:

a. Prevention of the spread of contamination by shutting down ventilation fans, applying absorbent material in the case of liquids, and roping off or barricading the area.

b. Immediate notification of the immediate supervisor and the on-site RSO.

c. Allowing no one to leave the adjacent area or facility until the person has been checked for contamination.

c. Making full use of radiation monitoring instruments and available assistance. Each step of the decontamination process will be monitored with appropriate instruments. One person should remain uncontaminated to operate monitoring instruments. Protective footwear, gloves, and respiratory equipment shall be used as needed.

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10. RADIATION SAFETY PROGRAM (continued)

H. DECONTAMINATION PROCEDURES (continued)

2. General Procedures for Decontamination of Personnel

a. Ordinarily, the same procedures used for personnel cleanliness will be sufficient to remove radioactive contaminants from the skin. Soap and water (sequestering agents and detergents) normally will remove greater than 99% of conatminants. If it is necessary to remove the remainder, agents containing chemicals such as citric acid, potassium permangenate, and sodium bisulfate can be used on the outer layers of skin where contamination remains. These agents will be applied with caution, if possible under medical supervision.

b. Remove any clothing or equipment found to be contaminated before determining levels of personal contamination.

c. Decontaminate first any areas of the body found to be significantly more contaminated than surrounding areas. This spot-cleaning approach is necessary to prevent the spread of existing contamination that might occur, for example, in showering.

d. If the contamination is general over the entire body, a thorough shower is necessary. Special attention will be paid to such areas as the hair, hands, and fingernails. After showering and monitoring, residual contamination can be removed by spot-cleaning.

e. Avoid the prolonged use of any one type of decontamination procedure: the effect may be to irritate and abrade the skin and thus render ineffective more suitable procedures.

f. Avoid the use of organic solvents, which may increase the penetrability of radionuclides through the outer skin layers.

g. Oxalic acid, which is a known toxin, will not be used under any circumstances for personnel decontamination.

h. Specific Procedures for Hand Decontamination:

1. Wash the skin thoroughly with a mildly abrasive soap and water, paying special attention to fingernails and areas between the fingers. Repeat the procedure if monitoring reveals remaining contamination.

2. Apply a sequestrant-detergent mixture, such as 5% water, 30% laundry detergent, 65% sequestering agent (such as Calgon), and 5% Carbose. Repeat the procedure if results are encouraging.

3. Apply a sequestrant-detergent cream, rubbing thoroughly into the skin for one minute. Repeat as long as the treatment shows that contaminants are being removed.

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10. RADIATION SAFETY PROGRAM (continued)

I. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS

Gas Chromatographic Equipment containing 63-Ni-based electron capture detectors are cleaned and tested for contamination on a semi-annual basis. Swabs utilized in the contamination test are sent to the off-site RSO Edmond J. Baratta for liquid scintillation counting.

General policies and procedures relating to radioactive materials in gas chromatographic detectors follows:

1. All radioactive foils to be used in gas chromatography cells must be shipped to the on-site RSO, or designated individual, who will maintain a file describing the type of source, identification number and location.

2. Each cell containing radioactive material will be permanently labeled with the radiation caution symbol of 10 CFR 20 and the words:

CAUTION:RADIOACTIVE MATERIAL

The identity and activity of the radioactive material shall appear on the label.

3. The radioactive material shall not be removed from its identifying cell except for cleaning in the manner prescribed below, and shall not be transferred to other cells.

4. The following information shall be attached to each gas chromatographic instrument which contains radioactive material:

This equipment contains a radioactive source registered with the RSO as required by license from the NRC. Notify the RSO before removing the source from this location or upon any change in custodial responsibility.

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10. RADIATION SAFETY PROGRAM (continued)

H. POLICY AND PROCEDURES FOR GAS CHROMATOGRAPHIC EQUIPMENT CONTAINING RADIOACTIVE MATERIALS (continued)

5. Gas chromatography cells shall be leak tested as specified in their license and in accordance with instructions promulgated by the off-site RSO.

6. All work on cells, such as cleaning and wipe testing, will be carried out in Hood A, as decribed in Item 9 of this application. Gloves shall be worn and absorbent paper shall be used during cleaning operations.

7. Liquids generated during the cleaning operation may be disposed of into the sanitary sewer with large quantities of water.

8. All gas chromatographs shall be operated below temperature limits set by the manufacturer of the detector cell.

9. Instructions for Wipe Testing of 63-Ni detectors:

a. Wipe tests will be performed at six month intervals on all detectors containing 63-Ni sources.

b. The Certificate of Inspection supplied with the detector gives the initial wipe test results. This information will be retained for inspection by the NRC. Succeeding wipe test will be performed at six month intervals. All wipe test results will be kept on file and accessible for review.

c. Use single tipped, sterile, disposable cotton swabs in 17 x 100 mm test tubes, individually wrapped (source: Curtin-Matheson Scientific, or equivalent).

d. Moisten tip of swab with solvent (methanol, acetone, or hexane).

e. Grasp the cell; rub the moistened tip of the swab over all outside surfaces of the detector and all areas immediately adjacent. Be particularly careful to include the outlet tube terminus.

f. Place the swab in a plastic case. Be careful not to touch cotton to the plastic.

g. Fill in information on inspection card certificate (Attachment 10-1).

h. Properly pack container with swab and card in a shipping conatiner. Mail by parcel post to the off-site RSO, Edmond J. Baratta, FDA, 109 Holton Street, Winchester, MA 01890.

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11. WASTE MANAGEMENT PROGRAM

A. Dispose of **dry, solid** radioactive waste and dry materials suspected of being contaminated in plastic bags labeled as to radionuclide, activity, date, and carrying the radioactivity warning statement.

B. Disposable syringes and sealed, capped vials containing residual fluids are disposed of as dry waste.

C. Contaminated syringes needles and pipettes will first be packaged or wrapped to prevent puncture accidents.

D. 32-Phosphorus, 35-Sulfur, and 125-Iodine waste shall be disposed of separated by radionuclide in plastic bags labeled with the radionuclide, activity level, and date. Individual bags will be consolidated in a plastic bin designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". This material will be held in the decay-in-storage area (see Part 9, Attachment B) for the following times periods (at least ten half-lives):

32-Phosphorus:	180 Days
35-Sulfur:	900 Days
125-Iodine:	600 Days

A log will be maintained of all waste held for decay-in-storage, which will indicate the radionuclide, activity level, date disposed, and the date for the end of the decay-in-storage period.

At the end of the decay-in-storage period for each bag, the bag will be surveyed at the surface with a GM-type survey meter. If the exposure reading is less than twice background at the surface of the bag, the waste will be disposed of as conventional trash, after first removing or defacing the Radiation Caution Warning and Symbol.

E. Radioactive waste **will not** be emptied into public sewers, as by flushing down sinks, without prior consent of the RSO. All disposals into public drains will be documented by the RSO as to the radionuclide, the date, the amount of activity, and the dilution factor.

F. 3-Hydrogen and 63-Nickel waste or materials contaminated with these isotopes, will be placed in a separate, shielded waste container designated for this purpose and prominently marked with the radiation caution symbol and "CAUTION: RADIOACTIVE MATERIAL". Liquid Scintillation Vials containing tritium liquid waste shall be capped. A log of all entries of

radionuclides, activity, and date will be kept. This material will be stored for a maximum of one year, and then disposed of by contract with a licensed commercial disposal firm. (GSX Services, Inc., 3527 Whiskey Bottom Road, Laurel, MD. 20707-9761 [EPA ID No. PA7470090062] is currently used for disposal all hazardous waste generated by the laboratory).

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03120
STATUS CODE: 2
FEE CATEGORY: EX 3P
EXP. DATE: 19890131
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: HEALTH & HUMAN SERVICES, DEPARTMENT
RECEIVED DATE: 890104
DOCKET NO: 3006213
CONTROL NO.: 110089
LICENSE NO.: 37-09752-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: _____
CHECK NO.: _____

3. COMMENTS

SIGNED _____
DATE 1/2/89

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

1. FEE CATEGORY AND AMOUNT: _____

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

3. OTHER _____
_____

SIGNED _____
DATE _____