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

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

APPLICATION FOR MATERIAL LICENSE

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

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 04-09763-01

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

Department of Health & Human Services
Public Health Service, Food & Drug
Administration, Los Angeles District
1521 W. Pico Blvd., Los Angeles, CA 90015

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

Department of Health & Human Services, Public Health Service, Food and Drug Administration, Los Angeles District, District Laboratory, 1521 W. Pico Blvd., Los Angeles, CA 90015

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Harvey Hundley, Lab Director; Milton Luke, Supervisory Chemist | TELEPHONE NUMBER: 213-252-7592

SUBMIT ITEMS 6 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	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. See Attached
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. See Attached	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. See Attached
9. FACILITIES AND EQUIPMENT. See Attached	10. RADIATION SAFETY PROGRAM. See Attached
11. WASTE MANAGEMENT. See Attached	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY: Exempted; AMOUNT ENCLOSED $: N/A

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 K. Hundley	Harvey K. Hundley	Laboratory Director	12/8/88

FOR NRC USE ONLY

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

Attachment to Application for Material License

5. Radioactive Material

a. Nickel - 63 — An NRC approved foil for plated surface. The H.P. Model 18803-60520(2)

The number of cells on hand will be equal to twice (2x) the number of Ni63 gas chromatography units (a working cell plus a spare or used cell, # cells total). Maximum activity on each foil in cell not to exceed ~~25~~ 15 m Ci. (9.25×10^8 Bq)

1. Foils to be maintained as integral part of detector cell. Cleaning of cell(s) (without removal of foil) shall be done according to manufacturer's specifications and procedures outlined in above memoranda (LIB 2151). where is this

2. Swipe tests of cells shall be done according to procedures in above memoranda (LIB-2151).

3. Intact cell(s) shall be exchanged with FDA/WEAC for clean unit(s)

b. Phosphorous-32 — Any 600 microcuries (1.85×10^7 Bq)

6. Purposes:

5-a&b For use in gas chromatography devices for sample analysis.

5c. For microbiological research, development, analyses and storage.

7. Harvey Hundley - Laboratory Director
Milton Luke - Supervisory Chemist — Ni-63 foil
Robert Hinken - Electronics Technician

Edward J. Baratta/Consultant RSO
Cirriculum Vitae of E.J. Baratta attached

8. Robert Hinken - GC detectors
Jerry Froberg - GC detectors
Greg Doose - GC detectors

Training: Personal training by Neil Gata
previous consultant
Radiation Safety Officer.

Marie Bendeck - FDA course
Foodborne Microbial Pathogens
Listeria testing, Gene Probe
Dates: 6/1/87-6/5/87

Richard Ruby - FDA course
Foodborne Microbial Pathogens
Listeria Testing, Gene Probe
Dates: 6/1/87-6/5/87

Elsie Dagdag - FDA course
Basic Microbiology
Dates: 7/11/88-7/22/88

Edward Higa - FDA course
Basic Microbiology
Dates: 7/11/88-7/22/88

9. GCs HP Model 5890A
HP Model 5840A

Beta Counter Survey Meter

Eberline - Model E-120 with Hand Probe HP-260 GM pancake

Beta Shields Nalgene - Bench Top Beta Shields

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

Basic Radiological Health
Computer Programming
Fundamentals of Laser Protection
Executive Management Seminar

STANDARD OPERATING PROCEDURE

RADIATION SAFETY PROGRAM

REFERENCE: "Radiation Safety Handbook for Ionizing and Non-Ionizing Radiation," USD, HEW, PHS, FDA, July 1975.

A. ORGANIZATION

The Los Angeles 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 in Los Angeles, CA. They will use the radioisotopes phosphorous-32 as a tracer in assay studies.

B. ON-SITE RADIATION SAFETY OFFICER

Mr. Edmond J. Baratta, Radiation Safety Officer, FDA/ORA/WEAC, will serve as consultant. His address is Winchester Engineering and Analytical Center, 109 Holton Street, Winchester, MA 01890.

The duties and responsibilities of the on-site Radiation Safety Officer (RSO) are:

1. To supervise the radiation monitoring of all personnel using phosphorous-32.

2. To instruct personnel in the proper use of phosphorous-32.

3. To receive, store, inspect and record all phosphorous-32.

4. To keep a current inventory of phosphorous-32.

5. To supervise decontamination in cases of accidents or incidents involving phosphorous-32.

6. To alter or order cessation of any operation that might result in hazardous incidents or releases of phosphorous-32.

This authority extends to those cases involving releases or contamination of radioactivity and shall involve actions that are either consistent with established radiation safety procedures and/or consistent with the prevention of injury to employees.

7. To maintain records of personnel exposure, routine laboratory monitoring, accident reports, all activities of the RSo, and 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 personnel follow the provisions of the Radiation Safety Procedures and the NRC license are followed.

10. To conduct a continuous program of radiation hazard evaluations and elimination.

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

C. PROCUREMENT OF RADIOACTIVE MATERIALS

Request for the procurement of phosphorous-32 must be submitted to the RSO for approval.

1. Procedures for the procurement of radioactive materials are:

   a. All requests for phosphorous-32 shall be submitted to the Radiation Safety Officer for approval.

   b. All radionuclides will be shipped directly to the Radiation Safety Officer who will log all pertinent information and prepare an inventory form (Appendix A) before delivering the shipment and inventory form to the user indicated on the request form.

   c. It shall be the responsibility of the radionuclide user to maintain a continuous inventory of each radionuclide in his or her possession and its disposition history by use on this form. Immediately upon final disposition of the nuclide he or she shall return the form to the RSO.

D. RADIATION AREAS

1. A "radiation area" is defined as any area accessible to personnel in which there exists 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 any one hour a dose in excess of 5 mrem, or in any 5 consecutive days a dose in excess of 100 mrem.

   a. Each radiation area shall be conspicuously posted with a sign(s) bearing the radiation symbol and the words:

CAUTION[1]
RADIATION AREA

2. 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 Appendix C shall be designated as "Restricted Area" and shall be conspicuously posted with a sign(s) bearing the radiation caution symbol and the words:

CAUTION[1]
RADIATION AREA

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

4. Containers

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 Appendix C shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

CAUTION[1]
RADIOACTIVE MATERIAL

5. Laboratory containers, such as beakers, flasks, and test tubes used transiently in laboratory procedures, do not require labels when the user is present. When such containers are to be left unattached for periods of eight (8) hours or more and contain material in concentrations greater than those specified in Column 2, Table 1, Appendix B, they will be labeled as described in subparagraph 4 of this part.

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

E. 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 his exposure to radiation as low as possible and, specifically, below the Maximum Permissible Exposures.

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

3. Each individual user shall utilize all appropriate protective measures including the following:

   a. Shall wear protective clothing whenever contamination is possible.

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

   c. Shall use pipette filling device. Never pipette radioactive liquids by mouth!

   d. Shall perform radioactive work within confines of an exhaust hood or glove box, unless approval has been granted by the RSO for working in the open.

4. Each user shall survey his hands, shoes, and body for contamination before leaving radiation areas.

5. No smoking or eating in areas where radioactive materials are present.

6. Maintain good personal hygiene.

   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. Should wash hands and arms thoroughly before handling any object which goes to the mouth, nose, or eyes.

7. Shall survey the immediate areas of hoods, benches, etc., during and after the use of radioactive materials. Any contamination should be removed immediately. If such removal is not possible, the area shall be clearly marked and the Radiation Safety Officer notified.

8. Shall keep the area containing radioactive materials neat and clean. The work area should be free of equipment and materials not required for the immediate procedure.

9. Shall store or transport materials in appropriate containers, preferably double containers, to prevent breakage or spillage and to insure adequate shielding.

10. Shall keep work surfaces covered with absorbent material and will employ Fiberglas splash trays or pans to limit and collect spillage in case of an accident.

11. Shall label and isolate radioactive waste and equipment, such as glassware, used for radioactive materials. Once equipment is used for radioactive substances, it shall not be used for other work or sent from the area to cleaning facilities, repair shops, or to surplus, until demonstrated to be free of contamination.

12. Shall report all accidental releases, inhalation, ingestion, or injury involving radioactive materials to his supervisor and the Radiation Safety Officer, and shall carry out their recommended corrective measures. Each individual shall cooperate in any and all attempts to evaluate his exposure.

13. Shall undertake decontamination procedures when necessary and will take the necessary steps to prevent any additional spread of contamination.

14. Refrigerators shall not be used jointly for foods and radioactive materials.

F. EMERGENCY PROCEDURES

Emergencies will generally be in the nature of spills, fires, or explosions, by which radioactive materials can be dispersed or released.

In case of emergency the following procedures shall be followed:

1. In the event of a fire, explosion, spill or hazardous malfunction, notify all persons to evacuate the area at once.

2. Notify the fire department if appropriate. Phone No.: ____#?

3. Notify the on-site RSO and immediate supervisor. RSO Office Phone: ____#? or Home Phone No.: ____#?

4. Attempt to extinguish fires if radiological hazard is not immediately present.

5. Shut off heating and air conditioning equipment if airborne contamination, if possible.

6. Monitor all persons involved in the emergency or control action.

7. Following the emergency, monitor the area and determine the protective devices necessary for safe decontamination. The RSO shall be available for this determination.

8. The responsible supervisor shall prepare a complete history of the emergency and subsequent activity including corrective and preventive actions taken related thereto for the RSO.

Note : Sections G. thru I not included in revised application

G. DECONTAMINATION PROCEDURES

General Principles

Successful decontamination calls for planned actions. A spur-of-the-moment action or attempt at decontamination can cause more harm than good. The person responsible for the spill in a contamination accident will usually take the first step 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 RSO. The first consideration will be personnel safety; persons not involved in the accident will leave the area. Subsequent considerations should involve the following procedures:

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

2. Immediately notify his or her immediate supervisor and the RSO.

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

4. Make full use of monitoring instruments and available assistance. Each step of the decontamination should be monitored. One person should remain uncontaminated to operate instruments and do other monitoring. When the instruments become contaminated, further progress is impaired. Protective clothing, footwear, gloves, and respiratory equipment shall be used as needed.

H. GENERAL PROCEDURES FOR PERSONNEL DECONTAMINATION

1. Ordinarily, the same procedures used for personnel cleanliness will suffice to remove radioactive contaminants from the skin, but the specific method will depend upon the form (grease, oil, etc.) of the deposited contamination. Soap and water (sequestering agents and detergents) normally remove more than 99% of the contaminants. If it is necessary to remove the remainder, chemicals can be used on the outer layers of skin upon which the contamination has been deposited. Because of the risk of injury to the skin surfaces, these chemicals (citric acid, potassium permanganate, sodium bisulfate, etc.) should be applied with caution, preferably under medical supervision. Types of lanolin-based creams are used to offset local irritations of skin surfaces after decontamination.

2. Remove any clothing or equipment found to be contaminated before determining levels of skin contamination.

3. Decontaminate any areas of the body found to be significantly higher than surrounding areas. This spot cleaning is necessary to prevent the spread of contamination to clean areas of the body that might occur in showering.

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

5. Avoid the prolonged use of any one method of decontamination. The effect from repeated ineffective decontamination methods may irritate the skin and thus hamper the success of more suitable decontamination procedures. No one chemical treatment is known to be specific for all of the elements with which one may become contaminated.

6. Avoid the use of organic solvents. Organic solvents may increase the probability of the radioactive materials penetrating through the pores of the skin. Oxalic acid is a poisonous compound, not to be used under any circumstances.

7. Specific Procedure for Hand Decontamination

   a. Wash the skin thoroughly with lava soap and water, paying special attention to areas between the fingers and around the fingernails. Repeat the procedure if monitoring indicates contamination remaining on the skin in amounts above tolerance.

   b. Apply a sequestrant-detergent liquid mixture (a 5% water solution of a mixture of 30% Tide, 65% Calgon, and 5% Carbose). Repeat the procedure if results prove encouraging.

   c. Apply a sequestrant-detergent cream (a 4% Carbose, 3% Versene, 8% water mixture). Rub thoroughly into the skin for approximately one minute. Repeat the treatment as long as the results show that the contaminant is being removed.

I. WASTE DISPOSAL

Dispose of DRY (SOLID) RADIOACTIVE WASTE (Phosphorous-32) and dry materials suspected of being contaminated in plastic bags labeled with the radioactive warning symbol. Solid waste, including con-

taminated disposable items such as gloves, waste paper, glassware, etc., will be stored in disposable polyethylene bags. Disposable syringes and tubes containing only the residual fluid are to be disposed of as dry waste. Contaminated needles and pipettes will first be boxed or prewrapped and then packed in plastic bags in order to prevent puncturing the contaminated bags and to protect personnel handling them.

The phosphorous-32 waste shall be monitored and set aside in a locked area marked "Radioactive Material." The material will be stored for 180 calendar days to allow for decay to background. After this period the material shall be surveyed. The background shall also be taken and both readings recorded. When the reading is less than twice background, the radioactive signs shall be destroyed and the waste discarded in conventional trash.

APPENDIX A

DHHS/PHS/FDA/EDRO

LOS-DO LABORATORY BRANCH

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

MAR 20 1989

Docket No. 030-03665
License No. 04-09763-01
Control No. 70823

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486

Attention: Harvey K. Hundley
Laboratory Director

Gentlemen:

This is in reference to the submittal of your application dated December 7, 1988 for renewal of your byproduct material license. In order to complete our review, we need the following additional information:

1. Item 7 of your application specifies Edward J. Baratta as the consultant Radiation Safety Officer (RSO) whose address is Winchester, Massachusetts. We normally do not allow consultants to act as the RSO unless they are readily available on-site for day-to-day operations involving licensed material. Please provide the name and description of the training and experience with radioactive materials of the individual who will perform the functions of the on-site RSO or person who will be responsible for implementing the radiation safety program.

2. Specify the name(s) of the person(s) who will supervise the use of nickel-63 foil sources. Also, specify the name(s) and describe the training and experience with radioactive materials of persons who will supervise the use of phosphorus-32 material.

3. You should provide an outline of the instruction and training which will be provided to your personnel using licensed material. The type of training that should be given is specified in 10 CFR Part 19.12 and described on pages 7-5 and 7-6 of Regulatory Guide 10.7, enclosed. Please provide the name and qualifications of the person providing the training, and confirm that such training will be provided to all personnel prior to their use of licensed material.

4. Describe the procedure that you will follow for safely opening packages containing unsealed licensed material. An acceptable procedure for receiving and opening packages containing radioactive material at nuclear medicine facilities is attached (Appendix F).

5. Specify the location (e.g. working area or laboratory) of your facility where radioactive materials will be used and stored. A drawing or sketch showing your use and storage locations would be helpful in describing your facility.

6. Paragraph E.7 of your "Standard Operating Procedure - Radiation Safety Program" states that surveys will be required before and after use of radioactive materials, but does not specify the type of surveys performed. These surveys should be performed daily with a low-range survey meter (e.g. thin-window pancake GM detector), and weekly with wipes for removable contamination during the use of phosphorus-32. You should revise and resubmit your survey procedures to include the type of surveys, counting instrumentation for evaluating wipes, the method of recording the data measured, and the action level which will require decontamination and re-survey. An acceptable procedure for area surveys at nuclear medicine facilities is attached (Appendix I) for your reference.

7. The survey meter (Eberline-120 with Hand Probe HP-260) specified in your application should be calibrated at least annually and after servicing. You should submit the name, address, and NRC or Agreement State license number of the firm which will calibrate your survey instrument. Also, please specify the calibration frequency and state that calibration records will be maintained for inspection purposes.

8. Paragraph D.2. of your "Standard Operating Procedure - Radiation Safety Program" specifies incorrect criteria for designating a "Restricted Area" and for posting areas or rooms with signs bearing the words "Caution - Radiation Area". As defined by 10 CFR 20.3(a)(14), a "Restricted Area" is any area access to which is controlled for purposes of radiation protection and does not specify any limiting quantity of licensed material. Paragraph D.2. should be revised by replacing your reference to signs containing the words "Caution - Radiation Area" with "Caution - Radioactive Material" in order to conform to the requirement of 10 CFR 20.203(e), and by omitting the phrase: "....designated as "Restricted Area" and shall be....".

9. Although Item 9 of your application identifies a "Nalgene-Bench Top Beta Shield", we can find no operating procedure in the application describing your use of beta shields when storing or handling phosphorus-32 material. Please amend and resubmit your operating procedure to include this instruction.

10. Please specify the name and NRC or Agreement State license number of the organization authorized to perform the analysis of leak test samples. If the analysis is performed in-house or by the FDA's Winchester Engineering and Analytical Center (WEAC) in Winchester, Ma., you should provide a description of the procedures employed by users in testing for leakage from nickel-63 foils using smears, and you should describe the method of analysis of the samples submitted. The measurements must be sufficiently sensitive to detect the presence of 0.005 microcuries or more of removable contamination.

MAR 20 1989

We will continue the review of your renewal request upon receipt of this information. In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate, and refer to Mail Control No. 70823.

Sincerely,

Robert D. Thomas, Chief
Nuclear Materials Safety
Section

Enclosures:
10 CFR Part 19
10 CFR Part 20
Regulatory Guide 10.7
Appendix I, Area Survey Procedures
Appendix F, Procedures for Safely
Opening Packages Containing Radioactive Material

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone: 213-894-3772

May 12, 1989

89 MAY 18 A10:07

RECEIVED
REGION V

Docket No. 030-03665
License No. 04-09763-01
Control No. 70823

Nuclear Regulatory Commission
Region V
1460 Maria Lane, Suite 210
Walnut Creek, CA 94596-5368
Attn: Mr. Robert D. Thomas

This is in reference to your letter of March 20, 1989 concerning additional informatuion necessary to complete your review of our byproduct material license.

1. Item 7 has been rewritten to specify the on-site RSO as Mr. Richard M. Ruby. In addition to the training listed, he will have a one week course in June in Radiation Safety at our WEAC facility in Boston, MA.

2. The revised item 7 now includes the persons responsible for the Nickel 63 foils (Mr. Jerry Froberg) and Mr. Richard M. Ruby and Marie S. Bendeck will be the major users or supervise the use of P32.

3. The revised item 8 now includes an outline of the instruction and training we will provide for our personnel.

4. We have adopted the procedures in appendix F and written it into our SOP.

5. Item 9 has been rewritten and a drawing of the area attached.

6. Paragraph E 7 of our SOP has been rewritten to provide surveys similar to those of Appendix I.

7. The survey meter will be sent to the manufacturer at least annually. Their name and address is included in the rewritten item 9.

8. Paragraph D 2 of our SOP has been rewritten to specify the signs "Caution Radiation Material"

FEE EXEMPT

70823

9. The SOP has been rewritten to include the routine use of beta shields when working with P32 material.

10. The WEAC facility has lic no. 030-04675 and they use the procedure described in Laboratory Information Bulletin (LIB) 2151 (attached to application).

We appreciate the great deal of help you have given us on this application and hope we have fulfilled all the necessary requirements for the license.

Sincerely,

Harvey K. Hundley
Laboratory Director

NRC FORM 313
10 CFR 30, 32, 33, 34, 35 and 40

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

APPLICATION FOR MATERIAL LICENSE

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

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 04-09763-01

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

Department of Health & Human Services
Public Health Service, Food & Drug
Administration, Los Angeles District
1521 W. Pico Blvd., Los Angeles, CA 90015

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

Department of Health & Human Services, Public Health Service, Food and Drug Administration, Los Angeles District, District Laboratory, 1521 W. Pico Blvd., Los Angeles, CA 90015

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Harvey Hundley, Lab Director
Milton Luke, Supervisory Chemist

TELEPHONE NUMBER: 213-252-7592

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

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

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

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

9. FACILITIES AND EQUIPMENT. See Attached

10. RADIATION SAFETY PROGRAM. See Attached

11. WASTE MANAGEMENT. See Attached

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: Exempted
AMOUNT ENCLOSED $: N/A

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

FOR NRC USE ONLY

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

Attachment to Application for Material License

5. Radioactive Material

a. Nickel - 63 An NRC approved foil for plated surface. The H.P. Model 18803-60520(2)

The number of cells on hand will be equal to twice (2x) the number of Ni63 gas chromatography units (a working cell plus a spare or used cell, # cells total). Maximum activity on each foil in cell not to exceed 25 m Ci. (9.25×10^8 Bq)

1. Foils to be maintained as integral part of detector cell. Cleaning of cell(s) (without removal of foil) shall be done according to manufacturer's specifications and procedures outlined in above memoranda (LIB 2151).

2. Swipe tests of cells shall be done according to procedures in above memoranda (LIB-2151).

3. Intact cell(s) shall be exchanged with FDA/WEAC for clean unit(s)

b. Phosphorous-32 Any 600 microcuries (1.85×10^7 Bq)

6. Purposes:

5-a&b For use in gas chromatography devices for sample analysis.

5c. For microbiological research, development, analyses and storage.

7. a. Nickel 63 Foils in GC Detectors

1. Jerry Froberg - Responsible for operation of all GC's

2. Robert Hinken - Responsible for swipe test of Nickel 63 GC Detectors

Personally trained by Neil Geta FDA's previous Radiation Safety Officer stationed at WEAC in the safe operation and uses of Nickel 63 electron capture detectors. He also covered the swipe testing which is described in LIB 2151 (attached).

Testing of swipes done at WEAC Lic# 030-04675

b. Phosphorus - 32

Richard M. Ruby is the on-site Radiation Safety Officer (RSO)

1. Marie S. Bendeck and Richard M. Ruby will be the principal users of the P^{32} probe, and will be responsible for radiological safety in the microbiology laboratory at Los Angeles. Their training is as follows:

Marie S. Bendeck: Attended headquarters sponsored (1 week course at FDA Cincinnati laboratory), "Listeria Gene Probe Course" in 1987. Three on-site laboratory sessions each approximately 3 hours was given and supervised by an experienced microbiologist. A half day session on radiation safety was presented which included the following topics:

1. Rules Govt. Agencies involved with Radiation
2. Responsibilities for Employer and Employee
3. Health Problems (P^{32})
4. Radiation Protection (General)
5. Radiation Protection (P^{32})
6. Monitoring
7. Emergencies
8. ALARA
9. Reg. Guide 8.13

Richard M. Ruby: Attended headquarters sponsored 3 day course, Genetic Detection of Pathogens, presented by Mr. Walter Hill in 1985. He received 2 hours of training on radiation safety.

In addition, Richard M. Ruby has 4 years and Marie S. Bendeck has 2 years of experience working with the P^{32} labeled DNA probe for regulatory analyses involving E. coli and Listeria monocytogenes in foods. Both microbiologists employ mathematical calculations to determine probe decay.

2. Mr. Edmond Baratta is our consultant R.S.O. - Refer to the attached license for his Curriculum Vitae. Richard M. Ruby will be the on site radiation safety officer (RSO).

8. Nickel 63 Electron Capture Detectors

Each person using the GC's will be trained in the safe operation and use of Nickel 63 electron capture detectors by Jerry Froberg.

Phosphorus - 32

Within the next few months we intend to have a short seminar on radiation safety covering the requirements under 10 CFR 19 for ancillary personnel. Thereafter, annual refresher seminars will be presented. Any new personnel will be given similar training by the Radiation Safety Officer as they arrive. The course outline is as follows:

1. Introduction to Radiation
2. Biological Effects
3. Radiation Uses and Natural Doses
4. Radiation Protection and Protection Standards
5. ALARA
6. Laboratory Safety Concerns

   a. Places where radiation is found in the laboratory show areas on a map.

   b. Warning signs

   c. Laboratory monitoring of areas where radiation is stored or used

   d. How does radiation at LOS-DO affect you?

   e. Tour of Laboratory

   f. Special consideration for janitors

   g. Special considerations
      -Receiving radioactive shipments
      -Sample Storage

   h. Special procedures for abnormalities (emergencies)

   i. 10 CFR 19 (special concerns)

9. Facilities and Equipment

   a. Nickel 63
      The nickel 63 foils are in Gas chromatographic detectors in Hewlet Packard models 5890A and 5840A.

   b. Phosphorus - 32

   1. Attach Drawings of facilities

   2. The Eberline - 120 with Hand Probe HP-260 will be used to monitor β radiation.

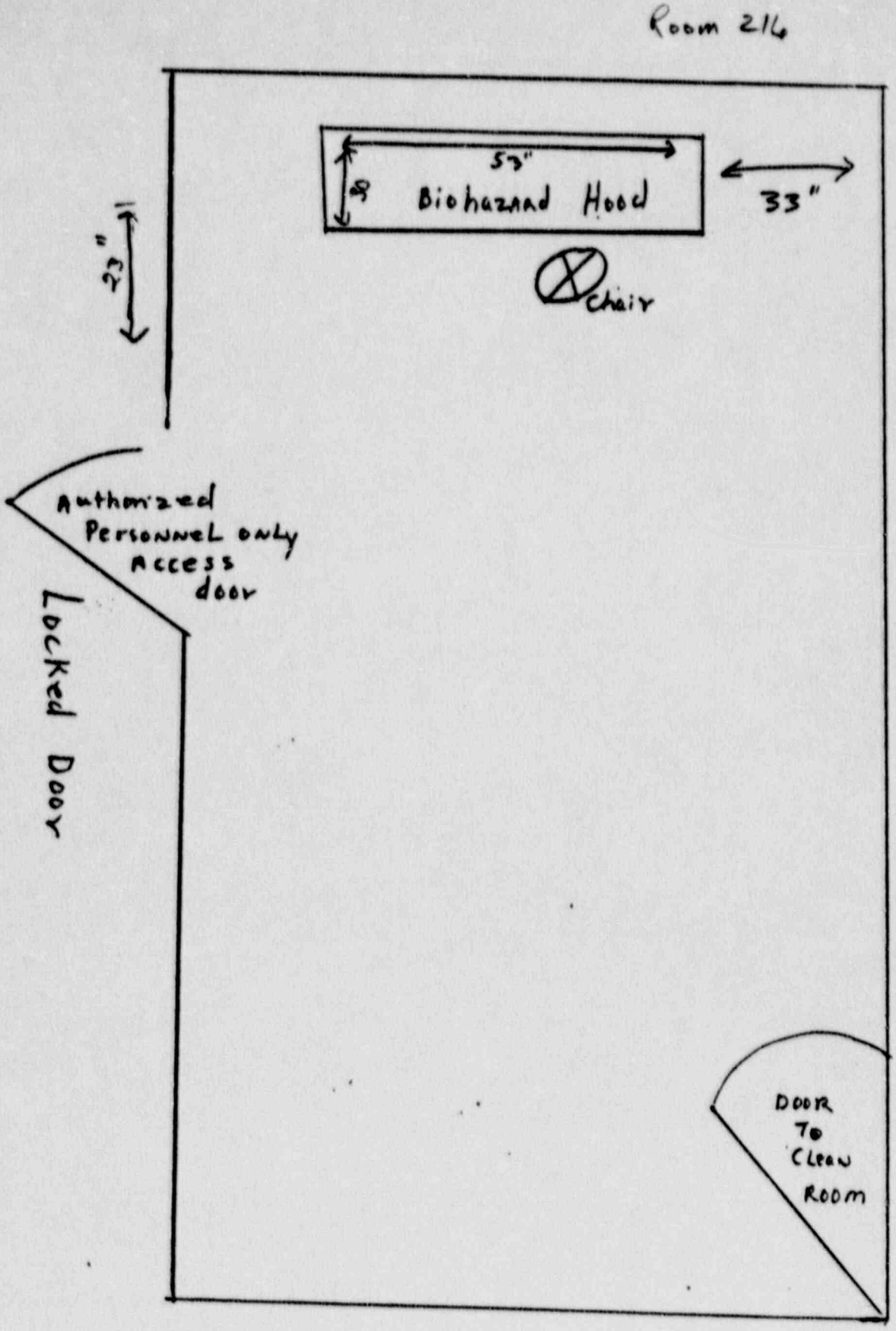
Eberline Instrument Corporation, Santa Fe, New Mexico will perform instrument calibrations at 6 month intervals. They will gamma calibrate the instruments with the CS-137 and also determine a Beta efficiency for P32.

Calibration records will be maintained for inspection purposes.

3. TLD Badges, both whole and body ring types will be used. They will be changed every 3 months (quarterly). Radiation Detection Company of Sunnyvale, CA will furnish the service.

4. Nalgene Bench top Beta Shield

9B.


Room 216
53"
9
Biohazard Hood
33"
Chair
27"
Authorized Personnel only Access door
Locked Door
Radiation Work Station
DOOR TO CLEAN ROOM

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

Basic Radiological Health
Computer Programming
Fundamentals of Laser Protection
Executive Management Seminar

LABORATORY INFORMATION BULLETIN

SERVICING TRITIUM AND NICKEL-63 ELECTRON CAPTURE DETECTORS

By

N. Gaeta, D. Young, S. Burraclough & H. Eidson

The purpose of this L.I.B. is to review current practices and to update information regarding the handling of tritium (^{3}H) and nickel-63 (^{63}Ni) radioactive sources.

When working with any type of radioactive material, the most prudent philosophy is to keep ones exposure to a minimum - As Low As Reasonably Achievable (ALARA).

The cleaning of a tritium detector is a routine maintenance operation in the FDA laboratory and with a few precautions one may be assured that a minimum of exposure from the uptake of radioactive material will occur during this operation.

EDRO/FSB/WEAC has provided a support function for the district laboratories for several years. A tritium foil repository is maintained at WEAC and nickel-63 electron capture detector units can be sent to the Winchester facility for cleaning and servicing.

Tritium and nickel-63 radioactive materials are regulated by the U.S. Nuclear Regulatory Commission (NRC) and the district laboratories are licensed by NRC with regards to the use and handling of these materials. WEAC has prepared a model license for use by the districts to amend their license which permits the district laboratories to clean tritium foils, exchange spent tritium foils for new foils, and to exchange intact nickel-63 detectors with WEAC for cleaning. District laboratories should be familiar with the requirements of their NRC licenses and be prepared to undergo an NRC audit.

I. TRITIUM ELECTRON CAPTURE DETECTORS

A. Handling and Shipment of Titanium Tritide ($Ti^{3}H$) Foils

Tritium foils ($Ti^{3}H$) are purchased in bulk from the manufacturer by FRST/EDRO. When received from the manufacturer, they are removed from their original glassine paper envelopes and replaced in new paper envelopes prior to shipment to the district laboratories.

Studies have shown that several microcuries of contamination may be on the original envelope. The new foils are packaged in glass jars with small packets of silica gel desiccant and the jar is appropriately labeled.

Appendix A, Attachment A (the format of which was improved by J. Burns, HUF-DO) is used for requesting new ^3H foils or for returning spent ^3H foils. Upon request, the glass jars are shipped in cardboard cylinders via certified mail(1). Shipping papers, Appendix A, Attachments B & C, for the transfer of the foils along with empty paper envelopes with foil number identification labels are also enclosed in the cardboard cylinders.

B. Cleaning Tritium Electron Capture Detectors

The most common modes of possible uptake of tritium in a district laboratory are by ingestion and inhalation. Prior to removing the electron capture (^3H) detector from the G.C., a work area should be established in a well-ventilated hood. The analyst should assemble all tools, reagents, solutions, materials and equipment in this one area. During the cleaning operation a "Caution - Radioactive Materials" sign should be displayed in this work area. A sheet of plastic-backed absorbent paper (available from laboratory supply houses) should be used as a work surface which can be disposed of at the end of the cleaning operation. A polyethylene or plastic trash bag should be readily available for all disposable materials.

Turn off supply voltage to the electron capture (^3H) detector and remove unit from the Gas Chromatograph using asbestos gloves. Place unit in a stand in the hood and allow to cool before opening. Use disposable gloves at all times when handling cool detector or foil. Remove screws, etc., and open (^3H) foil compartment. Cautiously remove tritium foil from the compartment with fine tipped stainless steel tweezers, and place it in a small disposable beaker or vial (liquid scintillation type is appropriate) containing sufficient ethyl acetate so that the foil is completely immersed. Place vial in an ultrasonic cleaner (100 Watt maximum output - do not use heat) for approximately 5 minutes. Support beaker or vial in such a way that it will not tip over in the ultrasonic cleaner. Remove foil from ethyl acetate, air dry and place the foil in a second vial containing sufficient (1+1) KOH & H_2O solution to completely immerse the foil. Repeat ultrasonic cleaning for 10-15 minutes. Remove foil from the vial, place in a large beaker in a sink and rinse with copious amounts of hot tap water, followed by distilled water and alcohol rinses. Allow to dry.

(1) In conformance with U.S. Post Office Regulations, Transport

While the foil is in the ultrasonic cleaner, the inside of the cell can be flooded with ethyl acetate and swabbed (2 or 3 times has been found sufficient in most instances) and the inlet and outlet arms are also rinsed with ethyl acetate.

The collector electrode should also be removed from the cap of the cell, rinsed with ethyl acetate, H_2O and acetone, polished using a fine piece of emery cloth and wiped clean. (If additional cleaning of the electrode is desired consult L.I.B. #1733.)

Rinse the cell cap with ethyl acetate.

After all parts of the cell have dried the detector is re-assembled. Reset the collector electrode tip at the top of the ^3H foil. Return cell unit to the G.C. and re-establish instrument operating parameters.

Studies have shown that up to 20 microcuries of ^3H can be released from the Ti^3H foil in the cleaning procedure. All aqueous liquid wastes can be discharged through a sink into a sanitary sewer followed by at least 10 liters of water. All solid wastes are bagged and discarded at the end of the cleaning operation into a conventional trash container.

NOTES:

1. Always use disposable gloves when handling cooled cell or the exposed foil. Frequent changes of gloves may be necessary to avoid cross contamination.

2. Fine pointed tweezers are usually required to remove the ^3H foil from the cell wall, however, once removed, tweezers with teflon coated tips or piece of teflon spaghetti covering the tips should be used whenever handling to prevent scratching the foil.

3. Any organic rinses or cleaning solvents which are not miscible with H_2O should be evaporated off in a hood in a disposable container.

4. After cleaning operation is concluded, rinse all reusable pieces of equipment i.e. tweezer, allen wrench, etc. with copious amounts of H_2O and dry with acetone.

5. All radioactive materials and equipments (tools, etc.) should be segregated from normal laboratory usage in a designated radioactivity storage area.

6. Place all disposable materials, i.e. sheet of plastic backed paper, beakers, etc., in plastic trash bag and finally remove disposable gloves. Place in trash bag, seal and dispose of in proper trash container.

7. Wash hands carefully and you can be sure your radiation exposure is ALARA.

C. Radiation Safety Studies - Shipping Containers, ^{3}H Release Rates, Room Air Concentration, Urine Bioassay

Swipe survey studies, using Whatman No. 1 filter paper, have been made of the entire package used in the exchange of foils from District labs, Appendix A, Attachment D & E. Only two of over 100 shipments showed removable ^{3}H contamination, on the outside of the package with the maximum being 0.0003 uCi. Samples are counted by liquid scintillation (using commercially available liquid scintillators) with minimum reported detectable activity being 0.00003 uCi (30 pCi). Levels between 0.0005 and 0.005 uCi of removable ^{3}H were found on the outside of five (5) glass jars, and one was as high as 0.011 uCi. In several cases removable contamination up to 0.001 uCi was found on packaging material and 0.0005 uCi on enclosed paperwork. These levels are traceable to the transfer of contamination by the analyst's handling of the foils. Proper techniques such as the use of disposable gloves with frequent changes, working in a hood on disposable paper whenever handling foils (in or out of their containers) can help to minimize the spread of contamination and prevent the material from getting inside the body.

A similar swipe survey of the container in which 50 foils (each 200 mCi/sq. in.) were received from the manufacturer showed contamination levels outside of the metal container - 0.0008 uCi; outside the glass jar holding foils - 0.02 uCi; and the glassine envelopes holding individual foils - 1 uCi. This again points out the need to use gloves and work on paper in the hood. The latter values of the glassine envelopes precipitated a program whereby the foils are removed from the glassine envelope and placed in a clean envelope prior to forwarding them to District labs. A second envelope is sent for the return of the foil.

Tritium ECD's are used in series with flame detectors. Studies were done in five (5) District labs, to determine the release of ^{3}H under operating conditions. Results of studies using $Ti^{3}H$ foils in ECD's operating at approximately 220°C, range from 0.024 uCi/min (old foils in use) to 1 uCi/min (immediately after new foils placed in service). Release rates drop by a factor of 10 within 20 hours of initial detector operation.

In all five (5) release rate studies the estimated ^{3}H air concentration in the G.C. rooms was below the recommended concentration guide for non-restricted areas. This was based upon the total number of detector units in the room and some unfavorable conditions of room size, air changes (3 per hour), and a 40 hour occupancy factor. To confirm the low air concentrations urine bioassay studies were done in three (3) Districts using liquid scintillation counting for ^{3}H in urine. The maximum level was 35 pCi ^{3}H/cc urine with three (3) other values from 13-19 pCi/cc and three (3) results less than 10 pCi/cc, the minimum detectable level. These compare with the occupational worker limit of 28,000 pCi/cc. It is recommended that initial urine studies be done at each District lab with yearly studies thereafter. Districts are requested to contact FRST/EDRO on this matter.

D. Scandium Tritide ($Sc^{3}H$)

A comparison of $Sc^{3}H$ versus $Ti^{3}H$ foils in the Barber Colman (pin-cup) detectors was made to investigate the possible replacement of $Ti^{3}H$ foils. $Sc^{3}H$ foils are stated as being capable of operation at elevated temperatures and this study was to show their performance at higher temperatures and to investigate cleaning of the foil by simply raising the temperature of the detector. A single study of release rates with a new $Sc^{3}H$ foil, gave a release rate of 12.5 uCi/min at 272°C and 1.4 uCi/min at 222°C. This release rate dropped to 0.15 uCi/min in 24 hours and stabilized at 0.05 uCi/min after several days. After cleaning this foil the release rate was measured at 16 uCi/min. This study was inconclusive and it is hoped that further studies will be made using Scandium foils.

II. NICKEL-63 DETECTORS

EDRO/ WEAC provides clean ^{63}Ni ECD's to all District and Headquarters laboratories. The detector is returned to the WEAC for exchange or cleaning. The units are shipped via certified mail and the necessary paperwork is shown in the Appendix, Attachment B & F.

Detector cells are taken apart under controlled conditions in a hood in the Center's hot lab. Foils are cleaned similarly to $Ti^{3}H$ foils, ethyl acetate cleaning in an ultrasonic bath for 15 minutes followed by warm KOH ultrasonic cleaning. Liquid wastes up to several microcuries are absorbed and disposed of as solid waste material. 100 gallons of dilution water would be necessary to discharge the liquid into the sanitary sewer but the concept of ALARA means that these liquid wastes can easily be handled as solid wastes at WEAC.

Two (2) release rate studies have shown no significant release of ^{63}Ni from these electron capture detectors. However, these are usually operated as a single unit, not in series with flame detector as are ^{3}H ECD's, and can be vented through a piece of tubing to an exhaust hood or to an outside window.

Swipe surveys of these ECD's,as required by NRC License for removable ^{63}Ni contamination are provided for each lab each January and July. Alcohol moistened swabs (cotton-tipped sticks) are used to rub over the detector, emphasizing potential leak areas, such as the output terminus and joints.

The swab, in a sealed tube, is mailed to WEAC for liquid scintillation counting. Most results have been reported as below the minimum detectable limit of 0.00002 uCi of removable ^{63}Ni contamination. A value of 0.005 uCi is the level considered to be a leaking cell.

Several ^{63}Ni detectors, from one manufacturing source, showed greater than 0.005 uCi of removable contamination. However, the contamination was traced to the foam rubber packing material used in the original shipping and storage container, and not to a detector leak.

III. SUMMARY AND CONCLUSIONS

District Labs are capable of cleaning $Ti^{3}H$ foils in electron capture detectors. It is necessary that individuals use disposable gloves at all times when they handle bare ^{3}H foils or foil container (cells, jars, envelopes). The ethyl acetate and KOH cleaning shall be done on plastic-lined absorbent paper in a hood. ECD's shall be vented through tubing outside of the room where possible. New foils should be stored under control conditions, preferably in an exhaust hood area All equipment (tweezers, allen wrenches, ect.) used in the cleaning of the foils shall be segregated from normal use in the laboratory and kept in the radioactivity storage area with the foils and spare cells. Used foils should be returned to WEAC as quickly as possible.

Swipes of ^{63}Ni ECD's must be performed each January and July. Swabs are forwarded to WEAC for liquid scintillation counting. Results to date, except one manufacturer, have shown no significant removable ^{63}Ni contamination.

Values for ^{3}H contamination levels, room air concentration, urine levels, the total result of all foil handlings and detector operation, give a ^{3}H body burden which compares favorably to the limit for the occupational worker of 2000 uCi. Values found are extremely low but today's philosophy of exposures, As Low As Reasonably Achievable, "ALARA" suggest that simple techniques of the use of gloves, control areas, and venting can reduce exposures to minimum values.

APPENDIX A, ATTACHMENT A

TRITIUM FOIL RETURN AND REQUEST FORM

NO. 2151
INSTRUMENTATION

INSTRUCTIONS:
1. ENTER THE NUMBER(S) OF THE SPENT FOIL(S) RETURNED IN PART A. (USE ADDITIONAL SHEETS IF NECESSARY)
2. IF NEW FOIL(S) ARE DESIRED, COMPLETE PART B.
3. SIGN AND DATE FORM.
4. RETURN FOIL(S) TO:

NEIL GAETA, HEALTH PHYSICIST
EDRO/WEAC, HFR-1300
109 HOLTON STREET
WINCHESTER, MASS. 01890
FTS 839-8712

LICENSE NO. 20-08361-01

PART A. SPENT FOILS RETURNED

FOIL NUMBER

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

ACKNOWLEDGED RECEIPT

NAME _____

DATE _____

PART B. NEW FOIL REQUEST. ISSUE ___ FOILS IN MY NAME AND SEND TO:

DISTRICT LAB AND ADDRESS

LICENSE NUMBER:

_____

NAME _____ DATE _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

WINCHESTER ENGINEERING AND
ANALYTICAL CENTER
109 HOLTON STREET
WINCHESTER, MASSACHUSETTS 01890
TELEPHONE: 617-729-8700

SHIPPER'S CERTIFICATE

THIS PARCEL CONTAINS AN EXEMPTED RADIOACTIVE DEVICE

RADIOACTIVE MATERIAL	NO.	ACTIVITY, mCi	TRANSPORT GROUP
NICKEL - 63 CELL			VII
TRITIUM (^3H) FOIL(S)			VII

NO LABEL REQUIRED

This is to certify that the above named article(s) are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to applicable regulations of the Department of Transportation, Post Office, and to the IATA Restricted Articles Regulations. This shipment is within the limitations prescribed for passenger-carrying aircraft.

DISTRICT_____ SHIPPING DATE _____

BY: Neil A. Gaeta
Neil A. Gaeta
Certified Health Physicist

Food and Drug Administration EDRO/WEAC 109 Holton Street Winchester, Mass.	TRITIUM FOIL ACCOUNTABILITY FORM

INSTRUCTIONS:

1. Sign and date lower portion of pink copy and return upon receipt of your order.
2. Retain white copy for your records.

ISSUED TO:

PER REQUEST OF	DATE

FOIL #	RELATIVE INTENSITY	DATE OF SURVEY	INITIALS

RECEIPT:

THE TRITIUM FOILS DESCRIBED ABOVE WERE RECEIVED IN GOOD CONDITION.

SIGNATURE DATE

RETURN TO:

NEIL GAETA, HEALTH PHYSICIST
EDRO/WEAC
109 HOLTON STREET
WINCHESTER, MASS. 01890

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

WINCHESTER ENGINEERING AND
ANALYTICAL CENTER
109 HOLTON STREET
WINCHESTER, MASSACHUSETTS 01890
TELEPHONE: 617-729-5700

District _____

Date _____

TRITIUM SURVEY OF PACKAGE USED TO RETURN USED ^{3}H FOILS

	Activity, uCi
Outside of Shipping Container	_____
Packing Material	_____
Outside of Glass Jar	_____
Inside Cover of Glass Jar	_____
Paper Envelope holding ^{3}H foil	_____
Paperwork in shipping container	_____

Comments _____

NDA = No Detectable Activity. This compares as less than the minimum reportable removable contamination level of 0.00003 uCi.

Reminder - Always use disposable gloves whenever handling bare ^{3}H foil. Wipe jar with clean moist tissues before packing.

Neil Gaeta, Health Physicist
EDRO/FSB/WEAC
FTS 839-8700

APPENDIX A, ATTACHMENT E

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Winchester Engineering and Analytical Center
109 Holton Street, Winchester, Mass. 01890

TO : Users of ^{3}H Foils for Gas Chromatographs

DATE: January 19, 1976

NO. 2151
INSTRUMENTATION
PAGE 11 of 12

FROM : Neil Gaeta, Health Physicist
EDRO/WEAC

SUBJECT: ^{3}H Foil Storage

Recent swipes of glassine envelopes used to hold new ^{3}H foils at WEAC showed removable contamination. As an added precaution against personnel contamination, new foils will be shipped in small paper envelopes. These are to be stored until ready to use, as outlined in previous memoranda.

An additional paper envelope is included with the accountability forms. When the new foil is ready for use, remove it from its original envelope and discard this envelope. The second, clean envelope can be taped alongside the GC and used to return the foil when it is spent. As before, disposable gloves are to be used whenever ^{3}H foils are handled.

Neil

Neil A. Gaeta

NICKEL-63 CELL EXCHANGE FORM

INSTRUCTIONS: (1) COMPLETE PART I AND FORWARD TO

NEIL GAETA, HEALTH PHYSICIST
EDRO/WEAC, HTR-1300
109 HOLTON STREET
WINCHESTER, MASS. 01890
FTS - 839-8712 , LIC. NO. 20-08564-01

(2) a. CLEAN CELL(S) WILL BE FORWARDED TO YOU, IF AVAILABLE.

b. ACKNOWLEDGE RECEIPT OF CELL(S), PART III

(3) COMPLETE AND SIGN PART II; RETURN WITH DIRTY CELLS.

(4) PART II WILL BE COMPLETED BY EDRO/WEAC AND A COPY RETURNED FOR YOUR RECORDS.

(5) MODIFY THESE ITEMS AS NECESSARY TO RETURN CELL FOR FOIL CLEANING ONLY, RETURNING CELL(S) WITH THIS FORM.

PART I

PLEASE EXCHANGE _____ CELL(S); CLEAN _____ CELL(S)

_____ DISTRICT, LICENSE NO. _____

PART II - Nickel-63 Cell(s) to EDRO/WEAC

Model Cell	Serial No.	WEAC Signature	Acknowledgements Date	District Signature	Date

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PART III - Nickel-63 Cell(s) from EDRO/WEAC

Model Cell	Serial No.	WEAC Signature	Acknowledgements Date	District Signature	Date

STANDARD OPERATING PROCEDURE

RADIATION SAFETY PROGRAM

REFERENCE: "Radiation Safety Handbook for Ionizing and Non-Ionizing Radiation," USD, HEW, PHS, FDA, July 1975.

A. ORGANIZATION

The Los Angeles 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 in Los Angeles, CA. They will use the radioisotopes phosphorous-32 as a tracer in assay studies.

B. ON-SITE RADIATION SAFETY OFFICER

Mr. Richard Ruby is the onsite Radiation Safety Officer.

Mr. Edmond J. Baratta, Radiation Safety Officer, FDA/ORA/WEAC/, will serve as consultant. His address is Winchester Engineering and Analytical Center, 109 Holton St., Winchester, MA 01890.

The duties and responsibilities of the on-site Radiation Safety Officer (RSO) are:

1. To supervise the radiation monitoring of all personnel using phosphorous-32

2. To instruct personnel in the proper use of phosphorous-32

3. To receive, store, inspect and record all phosphorous-32

4. To keep a current inventory of phosphorous-32

5. To supervise decontamination in cases of accidents or incidents involving phosphorous-32

6. To alter or order cessation of any operation that might result in hazardous incidents or release of phosphorous-32

This authority extends to those cases involving releases or contamination of radioactivity and shall involve actions that are either consistent with established radiation safety procedures and/or consistent with the prevention of injury to employees.

7. To maintain records of personnel exposure, routine laboratory monitoring, accident reports, all activities of the RSO, and 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 personnel follow the provisions of the Radiation Safety Procedures and the NRC license followed.

10. To conduct a continuous program of radiation hazard evaluations and elimination.

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

C. PROCUREMENT OF RADIOACTIVE MATERIALS

Request for the procurement of phosphorous-32 must be submitted to the RSO for approval.

1. Procedures for the procurement of radioactive materials are:

a. All requests for phosphorous-32 shall be submitted to the Radiation Safety Officer for approval.

b. All radionuclides will be shipped directly to the Radiation Safety Officer who will log all pertinent information and prepare an inventory form (Appendix A) before delivering the shipment and inventory form to the user indicated on the request form.

c. It shall be the responsibility of the radionuclide user to maintain a continuous inventory of each radionuclide in his or her possession and its disposition history by use on this form. Immediately upon final disposition of the nuclide he or she shall return the form to the RSO.

d. Procedures for Safely Opening Packages Containing Radioactive Material

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours,

in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200mR/hr at the package surface or 10mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

a. Put on gloves to prevent hand contamination

b. Visually inspect package for any sign of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. if > 10mR/hr, stop procedure and notify Radiation Safety Officer.

d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

e. Open the package with the following precautionary steps:

(1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

(2) Open inner package and verify that contents agree with those on the packing slip. Compare requisition, packing slip, and label on bottle.

(3) Check integrity of final source container (i.e. inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

(4) Check also that shipment does not exceed possession limits.

f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g. uCi/100cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

g. Monitor the packing material and packages for contamination before discarding.

(1) If contaminated, treat as radioactive waste.

(2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

D. RADIATION AREAS

1. A "radiation area" is defined as any area accessible to personnel in which there exists 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 any hour a dose in excess of 5 mrem, or in any 5 consecutive days a dose in excess of 100 mrem.

   a. Each radiation area shall be conspicuously posted with a sign(s) bearing the radiation symbol and the words:

   CAUTION[1]
   RADIATION AREA

2. Each area or room in which licensed material is used or stored and which contains any radioactive material shall be conspicuously posted with a sign(s) bearing the radiation caution symbol and the words:

   CAUTION[1]
   RADIOACTIVE MATERIAL

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

4. Containers

   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 Appendix C shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

   CAUTION[1]
   RADIOACTIVE MATERIAL

5. Laboratory containers, such as beakers, flasks, and test tubes used transiently in laboratory procedures, do not require labels when the user is present. When such containers are to be left unattached for periods of eight (8) hours or more and contain material in concentrations greater than those specified in Column 2, Table 1, Appendix B, they will be labeled as described in subparagraph 4 of this part.

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

E. 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 his exposure to radiation as low as possible specifically, below the Maximum Permissible Exposures.

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

3. Each individual user shall utilize all appropriate protective measure including the following:

   a. Shall wear protective clothing whenever contamination is possible.

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

   c. Shall use pipette filling device. Never pipette radioactive liquids by mouth!

   d. Shall perform radioactive work within confines of an exhaust hood or glove box, unless approval has been granted by the RSO for working in the open.

   e. The analyst will be working with exempt quantities (10uC) of P^{32}. However, we routinely employ (a) plexiglas shield, (b) monitor the work area and analyst with radiation meter after each use, (c) analyst wears a whole body radiation badge and finger ring with each use, (d) analysts routinely practice a brief mock run of the analysis and (e) safety glass of prescription eyeglass are always worn in the laboratory.

4. Each user shall survey his hands, shoes, and body for contamination before leaving radiation areas.

5. No smoking or eating in areas where radioactive materials are present.

6. Maintain good personal hygiene.

   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. Should wash hands and arms thoroughly before handling any object which goes to the mouth, nose, or eyes.

7. Shall survey the immediate areas of hoods, benches, etc., during and after the use of radioactive materials. Any contamination should be removed immediately. If such removal is not possible, the area shall be clearly marked and the Radiation Safety Officer notified. Every 3 months wipe surveys of the bench top working area and the storage area will be performed and checked with a liquid scintillation counter. If any contamination is detected that exceeds 1,000 DPM/100cm^2 (500×10^{-6} microcuries/100cm^2). The area or clothing will be decontaminated.

8. Shall keep the area containing radioactive materials neat and clean. The work area should be free of equipment and materials not required for the immediate procedure.

9. Shall store or transport materials in appropriate containers, preferably double containers, to prevent breakage or spillage and to insure adequate shielding.

10. Shall keep work surfaces covered with absorbent material and will employ Fiberglas splash trays or pans to limit and collect spillage in case of an accident.

11. Shall label and isolate radioactive waste and equipment, such as glassware, used for radioactive materials. Once equipment is used for radioactive substances, it shall not be used for other work or sent from the area to cleaning facilities, repair shops, or to surplus, until demonstrated to be free of contamination.

12. Shall report all accidental releases, inhalation, ingestion, or injury involving radioactive materials to his supervisor and the Radiation Safety Officer, and shall carry out their recommended corrective measures. Each individual shall cooperate in any and all attempts to evaluate his exposure.

13. Shall undertake decontamination procedures when necessary and will take the necessary steps to prevent any additional spread of contamination.

14. Refrigerators shall not be used jointly for foods and radioactive materials.

F. EMERGENCY PROCEDURES

Emergencies will generally be in the nature of spills, fires, or explosions, by which radioactive materials can be dispersed or released.

In case of emergency the following procedures shall be followed:

1. In the event of a fire, explosion, spill or hazardous malfunction, notify all persons to evacuate the area at once.

2. Notify the fire department in appropriate. Phone No.:_____

3. Notify the on-site RSO and immediate supervisor. RSO Office Phone: 983-7575 or Home Phone No.:_____

4. Attempt to extinguish fires if radiological hazard is not immediately present.

5. Shut off heating and air conditioning equipment if airborne contamination, if possible.

6. Monitor all persons involved in the emergency or control action.

7. Following the emergency, monitor the area and determine the protective devices if necessary for safe decontamination. The RSO shall be available for this determination.

8. The responsible supervisor shall prepare a complete history of the emergency and subsequent activity including corrective and preventive actions taken related thereto for the RSO.

APPENDIX A

DHHS/PHS/FDA/EDRO

LOS-DO LABORATORY BRANCH

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