



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

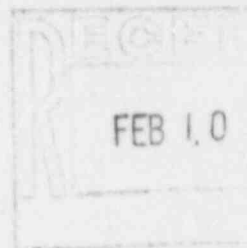
February 1, 1988

DEPARTMENT OF  
HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Building 20 - Denver Federal Center  
P.O. Box 25087  
Denver, CO 80225-0087

U.S. NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 Ryan Plaza Drive  
Suite 1000  
Arlington, Texas 76011

ATTENTION: CHARLES CAIN

REFERENCE: LICENSE 05-09749-01 AMENDMENT #12  
EXPIRATION DATE JULY 31, 1988



Dear Mr. Cain:

During July 1987, the Denver District Laboratory has relocated from the U.S. Customhouse, downtown Denver to the Denver Federal Center, Lakewood, Colorado. This is a request to amend and update the current license. The following information is provided.

1. A close-out survey was conducted at the U.S. Customhouse location. Swipes were taken on table tops where the gas chromatographs were located (Tables 1-6) and bench tops located in the Animal Drug Research Center (Benches 1-6) where tritium and carbon-14 experiments were conducted. Filter papers (2 cm diameter) were used to swipe an area of 10 cm square on each bench and table tops. These filter papers were immersed in scintillation counting fluid and counted in a Beckman LS 9000 Counter. All counts were at background levels (see Attachment A). The Nickel-63 detectors were swiped and sent to WEAC for counting during July 1987. No major radioactivity were noted. Also to note to date, iodine-125 was not used under the current license.

2. APPLICANTS NAME

FOOD AND DRUG ADMINISTRATION  
SOUTHWEST REGION, DENVER DISTRICT LABORATORY  
FTS 8-776-3000

3. NEW TELEPHONE NUMBER-SHIMODA

FTS-8-776-3070

4. MAILING ADDRESS (NEW)

DHHS/PHS/FOOD AND DRUG ADMINISTRATION  
BUILDING 20 DENVER FEDERAL CENTER  
POST OFFICE BOX 25087  
DENVER, COLORADO 80225-0087

FEE EXEMPT

5. ADDITION TO BY-PRODUCT, SOURCE

Add phosphorus-32 in any chemical form and the maximum possession at 10 millicuries for use in biological and biochemical research. Phosphorus-32 will be used in a DNA probe survey.

6. USER'S

Remove Marion K. Green name from the license and add Stephen R. Gray name to the license who had replaced Mr. Green.

Mr. Stephen R. Gray is the electronics technician on gas chromatographs containing radioactive detectors (nickel-63). He removes defective or installs new detectors. The defective detectors are sent to FDA, WEAC, Winchester, MA to be either cleaned or disposed of. Each of these detectors contain approximately 15 mCi nickel-63. Also, he will perform and conduct semi-annual swipe tests on these detectors. These swipes are sent to WEAC for analyses. Mr. Gray has received on-the-job training on instrument repair with FDA and the private sector over the last 17 years.

ADDITIONAL USERS- THEIR EXPERIENCE AND TRAINING:

ROBERT E. HAYMOND

Took the following courses, "Foodborne Microbial Pathogens: LISTERIA Testing and DNA Gene Probes" June 1-5, 1987 (40 hours) at the FDA Cincinnati District Laboratory, Cincinnati, Ohio. This course included actual lab "hands-on" experience, lectures, films and handouts pertaining to the safe handling of radioactive materials. The second course "DNA Probes for LISTERIA" November 16-19, 1987 (32 hours) was held at FDA, Washington D.C. (CFSAN) which included a lecture and a demonstration on the safe handling of radioactive probe materials.

JAMES C. ROMER

Mr. Romer also took the same course on "Foodborne Microbial: Pathogens LISTERIA TESTING AND DNA PROBES" and the information on this course is stated in Mr. Haymond's training.

7. RADIATION DETECTION INSTRUMENT

FDA purchased a LUDLUM model 3 survey meter, Sweetwater, Texas. The instrument was calibrated on 12/31/87 against cesium-137 and the next calibration is due a year later.

#### 8. PERSONNEL MONITORING DEVICES

These will be supplied by Edmond J. Baratta who replaced Neil Gaeta at WEAC. For the DNA P-32 probes, we will request ring film badges to be worn by the users.

#### 9. FACILITIES AND EQUIPMENT, ETC.

The Food and Drug Administration, Denver District Laboratory, is located at Building 20, Denver Federal Center, Lakewood, Colorado. See attachments B and C for location and laboratories involved.

Lab H1204, gas chromatographs

Lab H1212, gas chromatographs

Lab H1309, gas chromatograph

Lab H1405, gas chromatographs

Lab H1404, Beckman Counter and lab where P-32 studies will be conducted

Lab H1311, 3-H and 14-C studies (low level) will be conducted

Lab H1406, same as above

Rm H1517A, Radioactive waste storage area

#### 10. WASTE DISPOSAL

Radioactive wastes that meet the criteria for disposal shall be disposed as follows:

- a. Aqueous radioactive wastes that meet the criteria as set forth in Appendix B will be disposed via the sanitary sewer system.
- b. Liquid scintillation vials will be disposed if they meet the criteria as set forth in Federal Register Vol.46, No.47, Wed. March 11, 1981, 16230.
- c. Any other radioactive wastes will be disposed of according to the handbook entitled "Radiation Safety Handbook for Ionizing and Nonionizing Radiation" USDHEW, PHS, FDA, July 1975.

#### 11. RADIATION SAFETY

See attached standard operating procedure (SOP).

If there are any questions or comments on above request to amend the current license, please call me at FTS 776-3070 or write to me.

Sincerely,

*Wilbert Shimoda*

Wilbert Shimoda

Director, Animal Drug Research Center  
RSO, Denver District

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ANIMAL DRUG RESEARCH  
CENTER (ADRC)DENVER DISTRICT OFFICE  
EDRO/FDA/DHHSADRC LABORATORY NO. 2A. LIQUID SCINTILLATION  
COUNTER

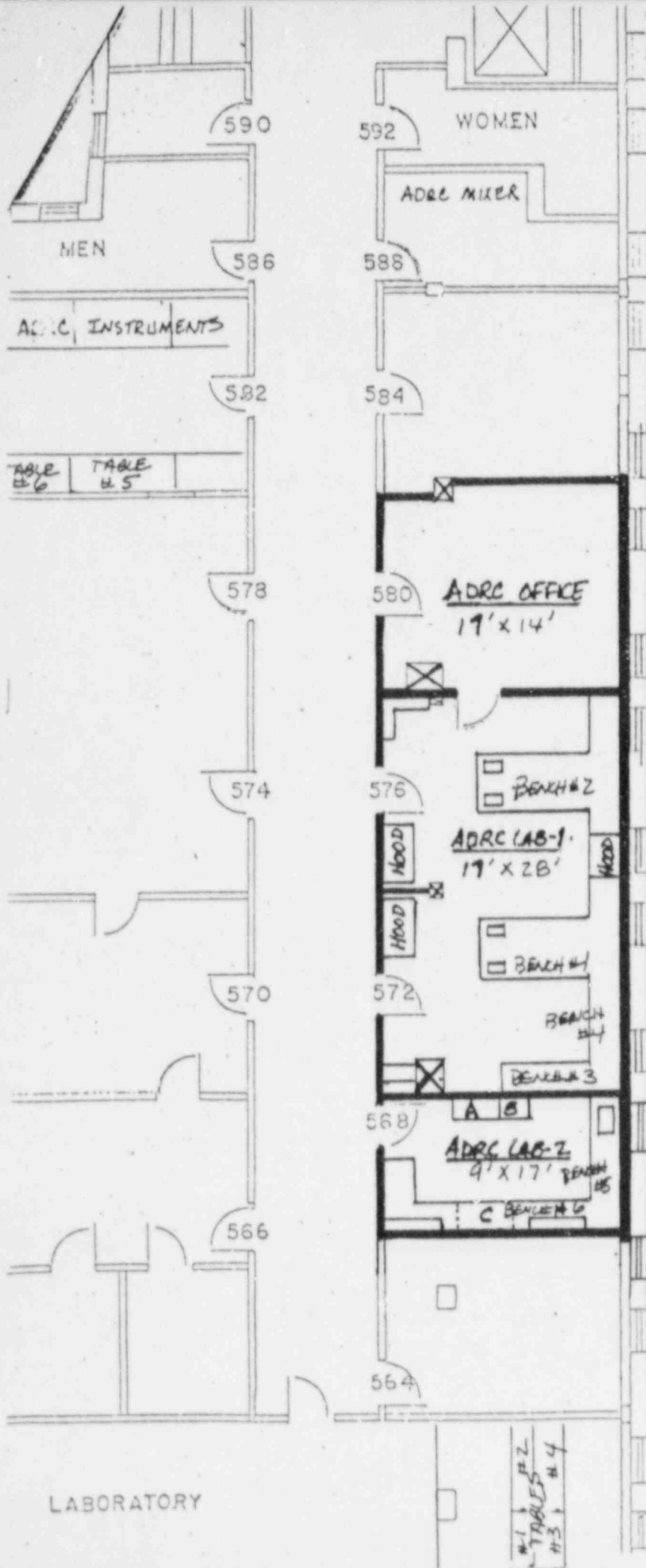
B. REFRIGERATOR

C. RADIOISOTOPE

GLOVE BOX WITH  
CHARCOAL FILTERCLOSE OUT SURVEY

TABLES AND BENCHES SWIPED  
WITH FILTER PAPER COVERING  
100 CM SQUARE (10 cm x cm)  
AREA. FILTER PAPER COUNTED  
IN SCINTILLATION LIQUID  
COUNTER. USED 3H and 14C  
WINDOWS. 10 MIN. TOTAL COUNT  
(CPM - AVE.)

	3H	14C
BLANK -	32	24
TABLE #1 -	34	30
TABLE #2 -	32	28
TABLE #3 -	33	25
TABLE #4 -	32	26
TABLE #5 -	27	26
TABLE #6 -	32	28
BENCH #1 -	32	26
BENCH #2 -	34	24
BENCH #3 -	30	26
BENCH #4 -	31	25
BENCH #5 -	29	26
BENCH #6 -	35	29

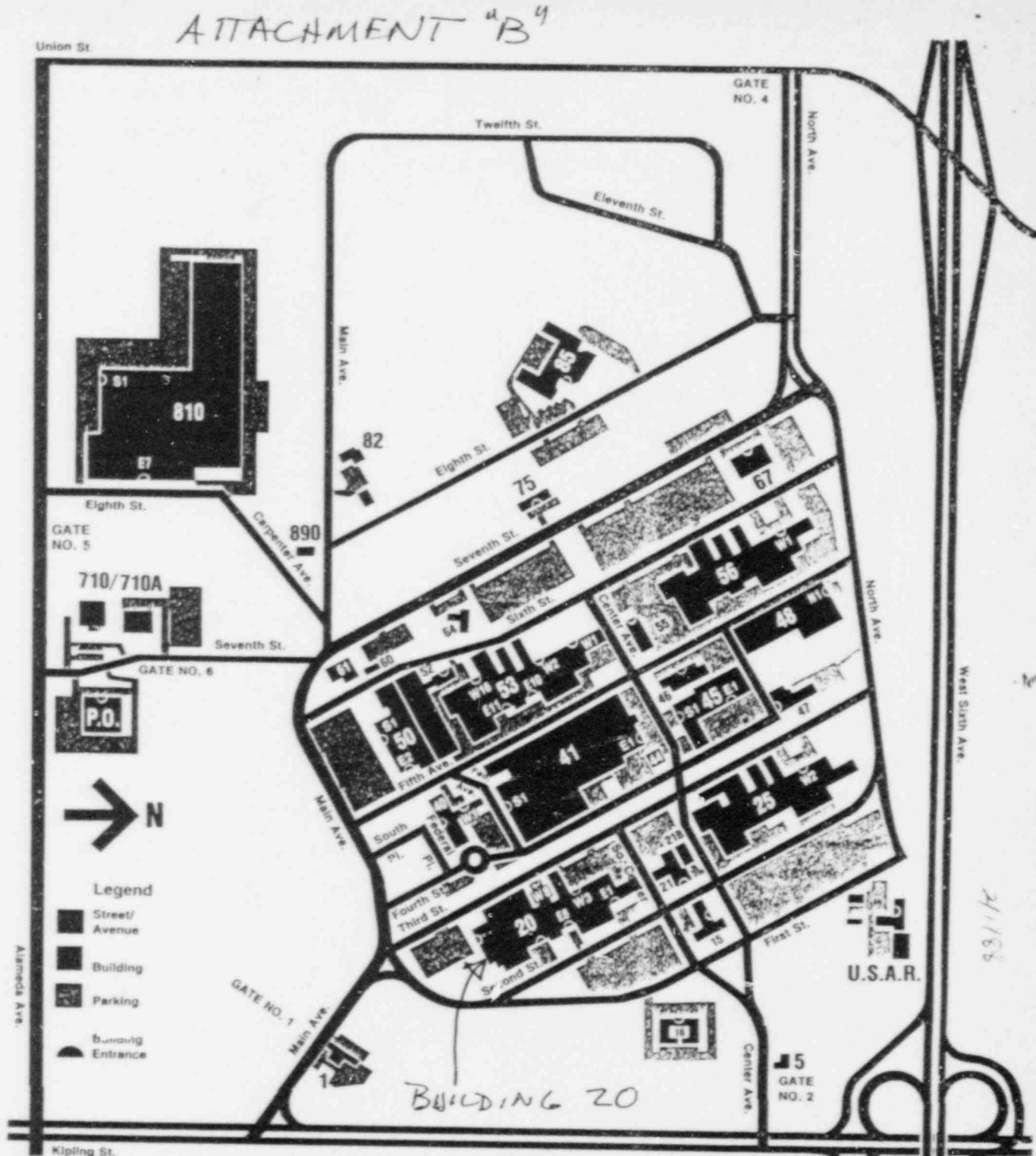


LABORATORY

# ALPHABETICAL DIRECTORY

BLDG. NO. AGENCY/ACTIVITY

- 82 BOR ENGINEERING & RESEARCH CENTER E16\*
- 84 BOR ENGINEERING & RESEARCH CENTER W1\*
- 87 BOR ENGINEERING & RESEARCH CENTER
- 88 BUREAU OF LAND MANAGEMENT S1\*
- 89 BUREAU OF LAND MANAGEMENT E1-S1\*
- 92 BUREAU OF LAND MANAGEMENT E5
- 98 BUREAU OF MINES E8\*
- 99 BUREAU OF MINES W16\*
- 41 CONSOLIDATED ADMIN. SUPPORT UNIT S1\*
- 95 ENVIRONMENTAL PROTECTION AGENCY W1\*
- 40 FEDERAL ARCHIVES & RECORDS N1\*
- 710/710A** FEDERAL EMERGENCY MANAGEMENT AGENCY
- 40 FEDERAL EMPLOYEE HEALTH UNIT W3\*
- 92 FEDERAL HIGHWAY ADMINISTRATION (FHA)
- 98 FOOD & DRUG ADMINISTRATION E8\*
- 40 FOREST SERVICE
- 41 GENERAL SERVICES ADMINISTRATION S1
- 92 GOVERNMENT PRINTING OFFICE W1-W2\*
- 42 GSA BOILER HOUSE
- 41 GSA BUILDINGS MANAGER E1\*
- 1 GSA LAW ENFORCEMENT INFORMATION
- 44 GSA FIRE DEPARTMENT
- 90 GSA LANDSCAPE/SNOWREMOVAL
- 40 GSA MOTOR EQUIPMENT SERVICE E1\*
- 90 GSA SUPPLY DISTRIBUTION S1\*
- 41 MINERALS MANAGEMENT SERVICES S1\*
- 90 MINERALS MANAGEMENT SERVICES W16\*
- 90 MMS ROYALTY MANAGEMENT PROGRAM
- 90 MINE SAFETY & HEALTH ADMINISTRATION W2\*
- 90 OFFICE OF SURFACE MINING E8\*
- U.S.A.R.** U.S. ARMY RESERVE TRAINING CENTER
- 90 USDA-ANIMAL DAMAGE CONTROL
- 90 USDA-ANIMAL DAMAGE CONTROL E8\*
- 90 U.S. GEOLOGICAL SURVEY W2\*
- 90 U.S. GEOLOGICAL SURVEY W2\*
- 90 USGS-MAP SALES E7\*
- 90 U.S. POST OFFICE



\* These letters and numbers indicate visitor entrances.  
You will find each one keyed to the map above.

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 Denver Field Office 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 Denver, Colorado. Within the Denver Field Office, the Animal Drug Research Center (ADRC) and Laboratory Branch (LB) will use certain radioisotopes as tracers or in assay studies. Radioisotopes in use will be Hydrogen 3, Carbon 14, Phosphorus 32, Iodine 125 and foils in electron capture detector cells shall be Nickel 63.

B. ON-SITE RADIATION SAFETY OFFICER (WILBERT SHIMODA)

Mr. Edward J. Baratta, Certified Health Physicist, FDA/ORA/WEAC, will serve as consultant. His address is Winchester Engineer 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 and facilities.
2. To instruct personnel in the proper use of radioactive material.
3. To approve all purchase requests for radioactive materials. Receive, store, inspect, and record all radioactive materials.
4. To keep a current inventory of radioactive materials.
5. To supervise decontamination in cases of accidents or incidents involving radioactive material.
6. To alter or order cessation of any operation that might result in hazardous incidents or releases of radioactive material.

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 all radioactive compounds, radioactive by-product materials and electron detector foils must be submitted to the RSO for approval.

1. Procedures for the procurement of radioactive materials are:
  - (a) All purchase order requests for radioactive materials shall be submitted to the Radiation Safety Officer for approval .
  - (b) Purchase requests (Form DHHS 393) shall contain the following information: name of radionuclide, amount in millicuries and the supplier.
  - (c) The RSO shall review the purchase order and if the amount of radioactive material requested does not exceed the amounts specified in the approved users form "Application to Use By-Product Material" and/or the NRC possession limits for that particular radionuclide, it will be approved and forwarded to the purchasing office.
  - (d) 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.
  - (e) 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 caution symbol and the words:

CAUTION<sup>1</sup>  
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<sup>1</sup>  
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 millirems 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<sup>1</sup>  
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 materials in concentrations greater than those specified in Col. 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.

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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

1. 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. 6444
3. Notify the on-site RSO and immediate supervisor. RSO Office Phone Local 63070 or Home Phone No. 360-9299.
4. Attempt to extinguish fires if radiological hazard is not immediately present.
5. Shut off heating and air conditioning equipment if airborne contamination is 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.

## G. DECONTAMINATION PROCEDURES

### A. 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

Radioactive wastes that meet the criteria for disposal shall be accumulated in 55 gallon drums. These drums will meet DOT requirements which are double plastic lined and containing absorbent material. Drum(s) will be stored in the Hazardous Waste Room, (H1517A) Building 20. On a yearly basis, these wastes shall be disposed of through Authorized Waste Disposal Service.

Dispose of LIQUID RADIOACTIVE WASTE IN THE LABELED GLASS OR PLASTIC JARS labeled with the radioactive warning sign. If the liquid waste container is glass, it must be set in a pan or other suitable container so that the contents will be retained if accidentally broken. Liquid waste containers must have a securely fitting cover, which must be kept closed. Plastic jugs should be stored in laboratory fume hood. Do not dispose of radioactive liquids down the sinks.

Do not remove LIQUID SCINTILLATION COCKTAIL LIQUIDS from LSC vials for disposal. Used LSC vials must be tightly capped and returned to cardboard trays labeled with the identity of the radionuclide for pickup by the radioactive waste contractor. Place in separate trays those vials containing less than 0.05  $\mu\text{Ci/g}$  of C-14 or H-3.

Dispose of DRY (SOLID) RADIOACTIVE WASTE and dry materials suspected of being contaminated in yellow plastic bags labeled with the radioactive warning symbol. Solid waste, including contaminated disposable items such as gloves, waste paper, glassware, etc., will be stored in yellow 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. Contaminated protective clothing will be disposed of as radioactive waste when no longer needed.

# APPENDIX A

DHHS/PHS/FDA/~~EDDO~~ OICA  
DEN-DO/ADRC

## Inventory of Radionuclides

User	Quantity	Supplier
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Date Received	Date Assayed	Half Life
---------------	--------------	-----------

	Quantity	Date	Location, Receiver and Remarks	Final Disposition
Original Balance				
Transferred				
New alance				
Transferred				
New Balance				
Transferred				
New Balance				
Transferred				
New Balanced				

RADIOISOTOPE

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