

# FDA/CFSAN

## STANDARD OPERATING PROCEDURES

FOR THE

## USE OF RADIOACTIVE MATERIALS

April 2, 1991

*B/S/P*

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This manual sets forth the radiation safety policy of the Center for Food Safety and Applied Nutrition.

All employees involved in radiation activities in the conduct of Center objectives are required to follow specific procedures and precautions regarding the possession and use of radioactive materials.

## RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) is responsible for the following:

- a. ensuring compliance with the NRC Broad Scope Materials License issued to FDA
- b. receiving, reviewing and approving all protocols for use of radioactive material
- c. performing general surveillance of all health physics activities including personnel monitoring
- d. furnishing advice to personnel on all aspects of radiation protection
- e. authorizing procurement, receiving and distributing of all radionuclides
- f. distributing, receiving personnel monitoring devices including maintaining records
- g. providing training for all radionuclide users
- h. monitoring the radioactive waste contract, evaluating contractor performance with respect to NRC, EPA and disposal facility requirements and regulations
- i. supervising and coordinating radioactive waste disposal procedures, including the maintenance of waste storage and disposal records
- j. maintaining an active inventory of all radioactive materials including amounts, radionuclides and locations
- k. providing supervision and assisting in the management of emergency, accident, spill or exposure situations
- l. preparing all license revisions and amendments

## RADIATION SAFETY COMMITTEE

The Center for Food Safety and Applied Nutrition (CFSAN) has a Type A Broad Scope License for the use of Radioactive Materials.

One condition of this type of license is the establishment of a Radiation Safety Committee. (10 CFR 33.13(c)(1)). The committee is composed of a Radiation Safety Officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials. The Committee is required to meet on a **quarterly** basis.

The Radiation Safety Committee is responsible for the establishment of appropriate administrative procedures to assure:

- 1) control of procurement and use of byproduct material;
- 2) completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures;
- 3) review, approval and recording of evaluations of proposed uses prepared in accordance with the paragraph above.

**The Radiation Safety Committee reviews the use of radioactive materials and reserves the right to revoke or suspend the privilege of obtaining or using radioactive material at any time. In addition, the Radiation Safety Officer has the responsibility to maintain health and safety standards.**

## RADIATION SAFETY COMMITTEE

The Radiation Safety Committee consists of the following members:

James Tanner, Ph.D., Chairman  
Chief, Nutrient Surveillance Branch  
Division of Nutrition, ONFS, HFF-266

Doris E. Waddick, Radiation Safety Officer  
Chief, Safety Management Branch  
Division of Administrative Operations, HFF-14

Walter H. Koch, Ph.D.  
Research Microbiologist  
Division of Microbiology, ONFS, HFF-235

Leonard Friedman, Ph.D.  
Metabolism Branch Head, In Vitro Metabolism Team  
Division of Toxicology, HFF-169

Joseph Hanig, Ph.D.  
Pharmacologist - Group Leader  
Division of Drug Biology, HFD-472

George Ikeda, Ph.D.  
Pharmacologist  
Metabolism Branch  
Division of Toxicology, HFF-169

Badaruddin Shaikh, Ph.D.  
Chief, Veterinary Pharmacology and Toxicology Branch  
Division of Veterinary Medical Research, HFV-520

Ken Ku  
Supervisory Chemist, Food Processing Section  
Division of Physical Sciences, HFF-413

## PRINCIPAL INVESTIGATOR RESPONSIBILITY

A **Principal Investigator** is a person who has been given approval by the Radiation Safety Committee to work independently with radioactive materials.

The Principal Investigator is responsible for:

1. Instructing those employees for whom they are responsible in the use of safe techniques and in the application of approved radiation safety practices and ensuring attendance in required radiation safety classes.
2. Complying with the regulations governing the use of radioactive materials, as established by the NRC and the CFSAN Radiation Safety Committee.
3. Recording the receipt, transfer and disposal of radioactive materials.
4. Performing laboratory surveys for radioactive contamination each time radioactive material is used and documenting the results in their FDA/CFSAN Radiation Safety Record Notebook.
5. Keeping their exposure to radiation "As Low As Reasonably Achievable."
6. Securing areas where radioactive materials are stored.
7. Notifying the RSO of changes in protocols.
8. Notifying the RSO of any radioactive material spills.
9. Ensuring that equipment is free of radioactive sources and contamination before releasing for repair or surplus.



## INDIVIDUAL RESPONSIBILITY

Each individual working with radioactive materials is responsible for:

1. Keeping his/her exposure to radiation as low as possible and specifically below the maximum permissible exposure as listed below:

### REMS PER CALENDAR QUARTER

Whole body; head and trunk;  
active blood forming organs;  
lens of eyes; or gonads..... 1 1/4

Hands and forearms; feet and  
ankles..... 18 3/4

Skin of whole body..... 7 1/2

2. Wearing TLD badges in radiation areas. Personnel who work only with pure alpha emitters or only with beta emitters having a maximum energy less than 0.2 MEV will not be required to wear TLD badges.
3. Surveying hands, shoes and body for radioactivity and removing any contamination before leaving the laboratory.
4. Utilizing time, distance and shielding to minimize exposure to radiation.
5. Complying with regulations governing the use of radioactive material as established by the NRC and the Radiation Safety Committee.
6. Reporting accidents resulting in the inhalation, ingestion or skin contamination to the RSO immediately.
7. Reporting missing radioactive material to the RSO.
8. Cleanup of contaminated equipment or areas is the responsibility of the persons creating the contamination and the Principal Investigator. It may not be assigned or delegated to ancillary personnel such as the Lab Services Branch, janitorial crew or maintenance workers.



## GENERAL REQUIREMENTS

### A. Signs and Labels

1. A "CAUTION RADIOACTIVE MATERIALS" sign shall be conspicuously posted on doors to laboratory areas where radioactive materials are being used or stored. An emergency sticker must also be posted with the name and home phone number of the individual responsible for the laboratory.
2. Storage areas shall be marked with a "CAUTION RADIOACTIVE MATERIALS" sign. In addition, containers in which materials are transported or stored shall be clearly labeled.
3. All equipment contaminated with radioactive material shall also be marked with signs or labels.

SIGNS AND LABELS ARE AVAILABLE FROM THE SAFETY OFFICE, ROOM 6113.

### B. Procedures/practices

1. Eating, drinking, smoking and applying cosmetics are not permitted in rooms posted for radionuclide use. **DO NOT** place containers from food or drink consumed elsewhere in the posted lab's trash can. It will be noted as presumptive evidence of eating in the lab.
2. Storage of food or drink is prohibited in posted labs, refrigerators, freezers and cold rooms used for work or storage of radioactive materials.
3. Mouth pipetting is not permitted.
4. Gloves and laboratory coat must be worn at all times when working with radioactive materials.
5. Utilize TIME, DISTANCE and SHIELDING when working with radioactive material to keep exposures "As Low As Reasonably Achievable" (ALARA).

6. Hands, shoes and clothing should be monitored for contamination with a survey meter before leaving the laboratory.
7. Surfaces in the immediate vicinity of work involving radioactive materials shall be covered with plastic-backed absorbent paper. Paper should be changed frequently. Where practical, an impervious tray should be used under the paper in order to ensure containment of spills.
8. Procedures involving aerosols, dusts or gaseous products, or procedures which might produce airborne contamination shall be conducted in a fume hood.
9. Hoods to be used for work with volatile forms of radioactive materials shall be tested by the Radiation Safety Officer to ensure that they meet the minimum requirements for air velocity at the face of the hood.
10. No one under the age of 18 years is permitted in areas where radioactive material is present.

C. Posting

1. Form NRC-3 shall be posted in rooms where radioactive material is used or stored in such a manner that it can be observed by persons entering or leaving the room.
2. Each lab shall have a notice posted stating the following:  

"As required by law, the following documents are available for review in room 6025, FB-8 at 200 C Street, S.W., by any individual working in FB-8, Division of Veterinary Medical Research and Beltsville Research Facility, Beltsville, MD.

10CFR19, 10CFR20, 10CFR21, USNRC Materials License, USNRC Violation, Radiation Safety Instructions."
3. Emergency notification home telephone number of the Principal Investigator shall be posted on the door of the lab.

## TRAINING

All personnel who work with radioactive material must be trained in the hazards associated with radioactive material and the correct procedures for working with radioactive material prior to beginning work (10 CFR 19). In addition to this initial training, workers are required to receive refresher training at least annually.

Before an individual can begin working with radioactive materials they should receive training in the following:

- a. principals and practices of radiation safety
- b. radioactivity measurements and monitoring techniques
- c. radiation calculations
- d. biological effects of radiation
- e. appropriate response to emergencies or unsafe conditions
- f. locations where copies of pertinent regulations are located
- g. rules and regulations of the license
- h. radioactive waste disposal guidelines

Contact the Safety Office at 245-1281 for information on available training classes.

# PROCUREMENT OF RADIOACTIVE MATERIAL

## ORDERING PROCEDURE

All radioactive material purchase orders must be approved by the Radiation Safety Officer (RSO) prior to placing an order with the vendor.

If an order is placed on a blanket purchase agreement, the RSO must be notified when the package is to be delivered. A copy of the BPA must be on file in the Safety Office.

All radioactive material orders must be delivered to the Safety Office, Room 6113. When placing an order the delivery address shall be:

**Radiation Safety Officer  
Food and Drug Administration  
Room 6113 (Inside Delivery)  
200 C Street, S.W.  
Washington, D.C. 20204**

The Principal Investigator is authorized for a specific amount of activity of a radionuclide when his/her protocol is approved by the Radiation Safety Committee. If the amount ordered exceeds this limit, the request for the order will be denied.

The RSO will monitor the outside of the package for radiation exposure and contamination. The Principal Investigator will be notified when the package is ready to be picked up.

An example of a properly prepared HHS-393 can be found in Appendix A.

Arrangements should be made with the vendor to have packages delivered during regular business hours. If a package is received after regular business hours, it should be placed in the 6th floor walk-in refrigerator.

## RECEIPT OF RADIOACTIVE MATERIAL

It is the responsibility of the Principal Investigator to monitor the contents of the package.

Use the following procedure for opening radioactive packages:

- a. Put on gloves to prevent hand contamination
- b. Open the outer package following the supplier's instructions if provided
- c. Open the inner package and verify that the contents agree with the packing slip and the material ordered
- d. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material
- e. If anything is other than expected, stop and notify the Radiation Safety Officer (RSO) at 245-1281
- f. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low background area. Assay the wipe to determine if there is any removable radioactivity by using the appropriate instrumentation
- g. Monitor the packing material and the empty package for contamination. If the package is not contaminated, remove or obliterate all radioactive labels and dispose of it in the regular trash. If contamination is detected, dispose of the package as radioactive waste

## RADIOACTIVE MATERIAL INVENTORY

Each Principal Investigator is responsible for maintaining an up-to-date inventory of the radioactive materials in their possession.

Each time a shipment of radioactive material is received, the Principal Investigator is given an inventory form (See Appendix B). When all the radioactive material from the shipment has been disposed of, the form should be returned to the Safety Office, HFF-14.

The Principal Investigator must complete an inventory form every six (6) months and submit it to the Safety Office when requested by the RSO.

## PERSONNEL MONITORING PROGRAM

The NRC requires that an individual be monitored for radiation exposure when an individual would likely to receive a dose in any calendar quarter in excess of 25 percent of the dose limit for occupational radiation workers (10 CFR 20.202).

To obtain a badge, an individual must complete a dosimetry form which is available from the Safety Office.

TLD badges will be assigned to those workers who work with high energy beta emitters such as  $^{32}\text{P}$  and gamma emitters. Those personnel who only work with  $^3\text{H}$ ,  $^{14}\text{C}$  or  $^{35}\text{S}$  are not required to have badges. Ring badges will also be assigned to those who work with high energy beta or gamma emitters.

The badges are exchanged **quarterly** (Jan/Mar/Jun/Sep). If an individual loses his/her badge, they should go to the Safety Office immediately to obtain a replacement. If a badge is lost for the whole quarter, an administrative dose will be assigned. A report describing the type of work the individual performed and the radionuclide(s) that were used during the quarter will be required to be completed by the individual and submitted to the RSO.

Badges should be worn on the trunk of the body between the neck and waist. Ring badges should be worn **under** gloves.

Do not store badges near sources of radiation when they are not being worn.

All records of radiation exposure are maintained in the Safety Office, room 6113 and may be reviewed by request. An individual's record of exposure can be obtained by request.



## LABORATORY SURVEYS

The immediate work areas (e.g., hoods, bench tops) in which radioactive materials are being used should be checked for contamination at least once daily by the Principal Investigator or radiation workers in the laboratory. In addition, these areas should be inspected each and every time there is reason to suspect a contamination incident. Records are to be maintained in the Investigator's FDA/CFSAN Radiation Safety Record Notebook.

In general, no radioactive contamination can be tolerated. Exceptions to this will include certain equipment which is used frequently for radioactive work and which is clearly marked with the standard radiation caution signs or labels. Any contamination that is not confined to protected surfaces should be cleaned immediately. The RSO will monitor and supervise the decontamination of such areas or equipment upon request.

Laboratory surveys are performed by a contractor on a monthly basis, however, **the Principal Investigator is responsible for performing his/her own surveys each time radioactive material is used.**

Survey results shall be recorded in disintegration per minute per 100 square centimeters (dpm/100 cm<sup>2</sup>). All records shall be kept in the CFSAN Radiation Safety Record Notebook which is issued to each Principal Investigator.

In order to maintain a Radiation Safety Program consistent with Federal Regulations, the Radiation Safety Office conducts regular inspections of all areas where radioactive material is used.

The results of these inspections and other applicable surveys will be incorporated into a quarterly inspection form and included in the annual report to the Radiation Safety Committee. A copy of the inspection form is attached as Appendix C.

## SURVEY INSTRUMENTS

1. Each laboratory (other than those where tritium is used exclusively) shall be equipped with a portable survey meter to be used for personnel and area monitoring. These portable survey meters (i.e. Ludlum 3) are available on loan from the Safety Office.
2. These survey meters are required to be calibrated every six (6) months. The Safety Office will notify the Principal Investigator when the instrument is to be picked up for calibration. It is the responsibility of the Principal Investigator to decontaminate the instrument, if necessary, before it is sent out for calibration.
3. When the meter is returned, the Principal Investigator will be given a copy of the calibration certificate. This certificate should be filed in the Radiation Safety Logbook.
4. Do not use an instrument with an out-of-date calibration sticker.

### Instructions for using instrument

1. Do a battery check.
2. Observe the behavior of the instrument after the range switch is turned to the desired setting. Do not use the instrument if there is any doubt as to its operational condition.
3. When finished, **TURN OFF**. Recheck the battery performance when finished to verify that the instrument is still working properly.

## RADIOACTIVE SPILL PROCEDURES

### Minor Spills and Contamination:

1. Put on gloves to prevent contamination of hands. Put on shoe covers.
2. Drop absorbent paper on spill to limit the spread of contamination.
3. Mark off contaminated area. Do not allow anyone to leave the contaminated area without being monitored.
4. Notify the Radiation Safety Officer.
5. Start decontamination procedures as soon as possible.
  - a. Use a detergent solution (i.e. radiacwash) and paper towels.
  - b. Place paper towels and any other contaminated materials in radioactive waste containers.
  - c. Start from the outermost edges of the contaminated area and work inward.
6. Monitor with wipes and/or portable survey instrument to ensure contamination has been removed.

### Personnel Decontamination:

1. Wet hands and apply detergent. Avoid the use of highly alkaline soaps or organic solvents.
2. Work up good lather. Rub gently for at least three (3) minutes. Apply water frequently.
3. Rinse thoroughly with lukewarm water.
4. Repeat several times as necessary.

## USE OF RADIOACTIVE MATERIAL IN ANIMALS

Animals shall be housed and handled in animal rooms specifically approved by the RSO. Rooms must be labeled with a "CAUTION RADIOACTIVE MATERIAL" sign and locked when unoccupied.

The cages used for housing the animals shall be posted with a "CAUTION RADIOACTIVE MATERIAL" label indicating the radionuclide that the animal has been dosed with. The floor area under the animal cages will be protected with absorbent paper and taped in place with radioactive warning symbol tape.

Animals care is the responsibility of the Principal Investigator. Non-radiation workers are not permitted to participate in their care unless they have been instructed in precautions to be taken and are approved by the RSO.

Workers will wear personal protective equipment such as lab coats, gloves and shoe covers when working in animal rooms.

All cages shall be monitored for contamination before being sent to the cage washing area. The Principal Investigator shall be responsible for cleaning cages contaminated with radioactive material. Cages shall be decontaminated to less than 100 dpm/100 cm<sup>2</sup>. Rinse solutions shall be considered as liquid radioactive waste.

All animal carcasses, animal waste, bedding, etc. shall be disposed of as radioactive waste (see section on Radioactive Waste Disposal).

## RADIOACTIVE WASTE DISPOSAL

Radioactive waste can be in one of four waste forms: a) dry solid b) bulk liquid (organic or aqueous), c) liquid scintillation vials or d) animal carcasses/tissue. The type of waste determines the method of disposal. **DO NOT MIX DIFFERENT TYPES OF WASTE!** Segregation of waste types is very important.

### I. Dry solid waste:

Dry solid waste is any dry, solid material such as absorbent paper, gloves, pipettes, glassware, etc. Dry solid waste shall not contain any liquid, animal or biohazardous waste. Biohazard bags are not to be used to dispose of radioactive material. Dry solid waste which contains Phosphorus-32 is stored for decay. Before disposing of this type of dry solid waste in waste containers all radioactive labels and symbols must be removed or obliterated. Waste containing other radionuclides is shipped for disposal through the radioactive waste contractor to a commercial disposal site. All waste containers must be labeled with a "Caution Radioactive Material" label, the name of the Principal Investigator, the date and the radionuclide. Sharp objects such as pipettes, syringes or broken glass must be packaged in cardboard or plastic boxes.

P-32 store for decay procedures: Do not mix any other radionuclides in with this dry solid waste. All radioactive labels, tapes, etc. must be removed or obliterated before waste is placed in the dry solid waste bags. If labels are found in the waste bags, they will not be picked up from the laboratory.

### II. Bulk Liquid Waste:

Bulk liquid waste can be one of two types: aqueous or organic

#### A. Aqueous:

Aqueous liquid is that liquid which is readily dispersible or soluble in water. It must have a pH between 6 and 10. This

waste is to be stored in FIVE (5) gallon plastic carboys available from the Safety Office. The container shall be labeled with a "Caution Radioactive Material" label in addition to the name of the Principal Investigator, the radionuclide, the activity and the date. Do not dispose of this waste down the sink drains! Do not generate any liquid waste with trichloroacetic acid or other acids. This is a "mixed" waste which no disposal facility will accept at present.

B. Organic:

Organic liquid must be stored in one gallon plastic containers. The container must be labeled with a "Caution Radioactive Material" label, the name of the Principal Investigator, the chemical constituent, the radionuclide, the activity and the date. The chemical identity is very important! If the chemical is a listed hazardous waste as defined by the Environmental Protection Agency (40 CFR 262), the liquid is a mixed waste and must be properly manifested for disposal.

III. Liquid Scintillation Vials:

Liquid scintillation vials should be tightly capped and returned to their original tray and stored in a ventilated area. The tray should be labeled with the radionuclide, the activity, the name of the cocktail or the chemical constituent, the name of the Principal Investigator and the date.

Liquid scintillation vials which contain  $^3\text{H}$  and/or  $^{14}\text{C}$  with activities of less than 0.05 microcuries per milliliter shall be segregated from vials containing other radionuclides or higher activities.

IV. Animal Carcasses:

FB-8:

Animal carcasses are to be placed in yellow polyethylene bags. Each carcass shall be double bagged. Each bag must be tagged or labeled



with the radionuclide, the activity averaged over the weight of the animal (uCi/g), the Principal Investigator and the date. Carcasses are to be stored in a designated freezer until they are picked up by the radioactive waste contractor.

Beltsville Research Facility:

Animal carcasses will be incinerated provided there is less than 0.05 microcuries of  $^3\text{H}$  and/or  $^{14}\text{C}$  per gram of animal tissue averaged over the weight of the animal.

Records of incineration will be maintained which include the date and maximum activity burned.

A radioactive waste pick-up can be requested by completing the Radioactive Waste Form and submitting it to the Safety Office, HFF-14.

V. Mixed Waste

**Definition:** A mixed waste is that waste which contains both a radioactive byproduct material and a listed hazardous chemical component.

**Management and disposal of Mixed Wastes must be conducted in compliance with the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) regulations.**

Because of this dual regulation, disposal facilities do not exist for some types of mixed wastes. Waste types must be carefully examined to ensure that mixed wastes which cannot be disposed of **are not generated.**



## SEALED SOURCES

1. All radioactive sealed sources must be received by the Radiation Safety Officer. Each source must be inventoried every six (6) months.
2. The RSO must be notified if equipment which contains a radioactive sealed source is to be moved or surplused. The source **must** be removed before equipment can be transferred to another facility or surplused.
3. Each sealed source containing radioactive material, other than  $^3\text{H}$  with a half-life greater than thirty (30) days and in any form other than gas will be tested for leakage an/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it will be tested for leakage before further use.
4. Records of leak tests shall be kept in units of microcuries and maintained by the RSO.
5. If the test reveals the presence of 0.005 microcuries or more of removable contamination the RSO shall immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with NRC regulations.
6. Any licensed sealed source is exempt from leak tests when the source contains 100 microcuries or less beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
8. Disposal of sealed sources shall be arranged with the Safety Office.

## APPLICATION TO USE RADIONUCLIDES

To become an authorized user of radioactive material, an investigator must first submit a completed application form, "Application to Use Radionuclides" to the Safety Office. This application will be reviewed by the Radiation Safety Committee provided the following conditions have been met:

- 1) the Principal Investigator has completed training and has experience in handling the types of radioactive material and the amounts of activity listed in the application;
- 2) adequate facilities for safely working with radioactive material, including fume hoods for airborne or volatile compounds and radiation detection equipment for surveying work areas;
- 3) the type of radioactive waste that is to be generated can be handled and disposed of with existing waste options.

The Committee approves Principal Investigators on a protocol by protocol basis for an annual amount (activity) of radioactive material. Each authorization is reviewed annually. Amendments to original authorizations may be made in the form of a memo to the RSO stating the reasons for changes.

## INSTRUCTIONS FOR COMPLETING THE APPLICATION

The application must include:

1. the Name of the Principal Investigator
2. the title of the Project
3. the radionuclide(s) and the chemical compound
4. the activity per experiment and the amount to be used in a one (1) year period
5. the room(s) where work with radioactive material will be performed and/or stored
6. the instruments that will be used for monitoring for contamination such as geiger counters, liquid scintillations counters, etc
7. the personnel monitoring that will be utilized which is determined by the radionuclide and activity
8. the protective equipment to be used for the protection lab personnel such as lab coats, gloves and shielding
9. the names of all personnel that will be working on the project
10. a brief summary of the project which includes how the radioactive material will be handled from the time it is received until disposal
11. a brief statement on how exposures to radiation will be "As Low As Reasonably Achievable" (ALARA)
12. the radioactive waste that will be generated including; the volume per month that is expected to be generated as well as the specific chemical constituents that will be present
13. the training and experience of the principal investigator and all personnel listed on the project; exact dates and locations of training

and experience a list of radionuclides and maximum activities used as well as the types projects performed

14. a declaration of use of any carcinogen
15. all applicable signatures.

The application should be signed by the Principal Investigator, his/her supervisor and the Radiation Safety Committee representative for the Division.

The application should then be submitted to the Radiation Safety Officer. After the RSO reviews the application for completeness it is sent to the Radiation Safety Committee for review.

Once an application has been approved by the Radiation Safety Committee, the Principal Investigator will be notified. This approval is effective for three (3) years or the duration of the protocol, whichever is less. The RSO shall be notified of any changes to the approved protocol in the form of an amendment request.

DEPARTMENT OF  
HEALTH AND HUMAN SERVICES  
PURCHASE/SERVICE/STOCK REQUISITION

REQUISITION NUMBER  
**276348**  
OFFICE CODE/SYMBOL

BPA and Call No. \_\_\_\_\_

TO HHS Procurement HFA-266 REQUESTING ORGANIZATION	REQUEST FOR <input checked="" type="checkbox"/> PURCHASE <input type="checkbox"/> SERVICE <input type="checkbox"/> STOCK ISSUE <input type="checkbox"/> RENTAL/LEASE
Food and Drug Administration FOR REFERENCE CALL	CUSTODIAL AREA
<u>Principal Radioisotope User</u> DELIVER TO	DATE
Food and Drug Administration Safety Office, Room <u>6113</u> 200 C Street, SW Washington, DC 20204	OBJECT CLASS
	EXTENSION
	APPROPRIATION
	CAN
	DATE REQUIRED

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST	
				UNIT	TOTAL
NET-027	<sup>3</sup> H - Thymidine, 5 mCi	1	vial		\$184.00
NFG-002H	<sup>32</sup> P - Adenosine 5'-triphosphate, tetra (triethylammonium) salt, 1 mCi	1	vial		\$368.00
<u>RADIOACTIVE MATERIAL</u> Route thru Radiation Safety Officer (HFF-14), Room 6025 for approval and signature  Source: New England Nuclear 549 Albany Street Boston, MA 02115					

I certify that the property/services requested are required for Government business, and are not available from stocks or current assets.*	FUNDS AVAILABLE (Signature/Title)	DATE	TOTAL	\$552.00
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REQUESTED BY (Signature/Title)* Principal Radioisotope User	DATE	RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.
RECOMMENDING APPROVAL (Signature/Title)*	DATE	RECEIVING OFFICIAL (Signature/Title)
APPROVAL (Signature/Title)*	DATE	ORDER NO. (PO, DO, FEDSTRIP, ETC.)
Administrative Officer	DATE	ORDER DATE
Administrative Officer (Signature)*	DATE	VOUCHER NO.
		VOUCHER DATE



# Memorandum

Date

From

Subject Chemical Carcinogens

To CFSAN Quality Assurance Staff

- \_\_\_\_\_ 1. I have reviewed the attached list of chemical carcinogens and concluded that none of these substances are to be used as the test subject or in any other way in this protocol or experiment.
- \_\_\_\_\_ 2. I have reviewed the attached list of chemical carcinogens. The test subject of this study is listed in the OSHA \_\_\_\_\_, IARC \_\_\_\_\_, and / or NTP \_\_\_\_\_ list(s).
- \_\_\_\_\_ 3. I have reviewed the attached list of chemical carcinogens and concluded that in this study one or more of the carcinogens are to be used, OSHA \_\_\_\_\_, IARC \_\_\_\_\_, NTP \_\_\_\_\_, Substance(s) \_\_\_\_\_
- \_\_\_\_\_

\_\_\_\_\_  
Signature



APPLICATION TO USE RADIONUCLIDES

NAME OF PRINCIPAL RADIONUCLIDE USER: \_\_\_\_\_

PHONE: \_\_\_\_\_ ORG. (DIV/BRANCH): \_\_\_\_\_

PROJECT TITLE: \_\_\_\_\_

START DATE: \_\_\_\_\_ ESTIMATED COMPLETION DATE: \_\_\_\_\_

RADIONUCLIDE(1): \_\_\_\_\_ CHEMICAL COMPOUND: \_\_\_\_\_

ACTIVITY (MAXIMUM AMOUNT TO BE USED PER YEAR): \_\_\_\_\_

ACTIVITY PER EXPERIMENT: \_\_\_\_\_

RADIONUCLIDE(2): \_\_\_\_\_ CHEMICAL COMPOUND: \_\_\_\_\_

ACTIVITY (MAXIMUM AMOUNT TO BE USED PER YEAR): \_\_\_\_\_

ACTIVITY PER EXPERIMENT: \_\_\_\_\_

ROOMS WHERE RADIONUCLIDE(S) WILL BE USED: \_\_\_\_\_

STORAGE AREAS: \_\_\_\_\_ HOOD USED: \_\_\_\_\_

RADIATION DETECTION INSTRUMENTS:

TYPE: \_\_\_\_\_ MODEL: \_\_\_\_\_ SERIAL NO.: \_\_\_\_\_

TYPE: \_\_\_\_\_ MODEL: \_\_\_\_\_ SERIAL NO.: \_\_\_\_\_

PERSONNEL MONITORING: \_\_\_\_\_ PROTECTIVE EQUIPMENT: \_\_\_\_\_

OTHER PERSONNEL ON PROJECT (Attach Qualification Form for Each):

\_\_\_\_\_  
\_\_\_\_\_

I HAVE RECEIVED, READ, AND WILL ADHERE TO "FDA/CFSAN STANDARD OPERATING PROCEDURES FOR THE USE OF RADIOACTIVE MATERIALS." I WILL ENSURE THAT PEOPLE WORKING UNDER ME WILL ADHERE TO THESE RULES. I UNDERSTAND THAT VIOLATION OF ANY OF THESE REGULATIONS MAY RESULT IN THE WITHDRAWAL OF APPROVAL TO USE RADIONUCLIDES.

SIGNATURE: \_\_\_\_\_ DATE \_\_\_\_\_

STUDY REVIEWED BY: \_\_\_\_\_ SUPERVISOR: \_\_\_\_\_ DATE \_\_\_\_\_

DIV. MEMBER, RADIATION SAFETY COMMITTEE: \_\_\_\_\_ DATE \_\_\_\_\_

STUDY APPROVALS: RADIATION SAFETY OFFICER: \_\_\_\_\_ DATE \_\_\_\_\_

CHAIRMAN, RADIATION SAFETY COMMITTEE: \_\_\_\_\_ DATE \_\_\_\_\_

CONDITIONS OF APPROVAL/COMMENTS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



**PROTOCOL:** Describe the radiation safety plan for the study. Include:  
how the radioactive material will be used  
how it will be handled  
the amount of activity that will be used per procedure  
where it will be used/stored  
how and where the waste will be stored.

**ALARA:** (Describe the procedures and survey program that will be instituted to ensure exposure to workers and the public will be "As Low As Reasonably Achievable.")

**RADIOACTIVE WASTE** (Estimate amount produced per month):

<u>Type</u>	<u>Amount (volume)</u>	<u>Chemical**</u>
Dry Solid	_____	_____
Aqueous Liquid	_____	_____
Organic Liquid	_____	_____
LSV (H-3 and/or C-14)	_____	_____
LSV (Other)	_____	_____
LSV (biodegradable)	_____	_____
Animal Carcasses	_____	_____

\*Please specify chemical, biological or hazardous material mixed with radioactive waste.

\*\*Indicate the amount or percentage of the chemical constituent that will be present.

DIAGRAM OF LABORATORY ARE. 5):

## QUALIFICATIONS OF RADIONUCLIDE USERS

DATE:	PHONE:	MAILCODE:	DIVISION:
NAME:	JOB TITLE:	BIRTHDATE:	SSN:
LIST RADIONUCLIDES TO BE USED:		PRINCIPAL INVESTIGATOR:	

### TRAINING AND EXPERIENCE

TYPE OF TRAINING AND COURSE TITLE	SPONSOR/LOCATION	DATES	LENGTH
PRINCIPLES AND PRACTICES OF RADIATION PROTECTION COURSE TITLE:			
B. RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES COURSE TITLE:			
C. MATHEMATIC / CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY COURSE TITLE:			
D. BIOLOGICAL EFFECTS OF RADIATION COURSE TITLE:			

RADIONUCLIDE	MAXIMUM ACTIVITY USED	WHERE	DATES USED	TYPE OF USE

SUPERVISOR'S SIGNATURE: \_\_\_\_\_

PRINCIPAL INVESTIGATOR'S SIGNATURE: \_\_\_\_\_