BRISTOL-MYERS COMPANY
PHARMACEUTICAL RESEARCH and DEVELOPMENT DIVISION
EVANSVILLE, INDIANA 47721 / ☎ (812) 426-6000

June 5, 1984

Dr. William J. Adam
Materials Licensing Section
Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Dr. Adam:

This correspondence is in regard to our request for renewal of License Number 13-00772-02, control number 75020. In your letter of May 17, 1984, you cited nine items which needed further explanation or clarification. Those points are addressed below:

1. This comment concerns Dr. Dischino's experience in handling radioisotopes.

   While an undergraduate and graduate student, Dr. Dischino's research efforts required handling C-11, O-15 and F-18 in quantities of 1 Curie, 100 mCi and 100 mCi, respectively. The above three isotopes decay by positron emission with an Emax of the particle equal to approximately 1 MeV. After slowing down to thermal energy, the positron then annihilates with an electron resulting in the production of two 511 KeV gamma rays.

   While a graduate student, Dr. Dischino completed four credit hours in radiochemistry laboratory techniques. He was subsequently assigned as a teaching assistant in that course. During the course he gained experience in handling C-14, Pa-234m, Ce-144, Pr-144, Co-60 and I-131. These isotopes were handled in quantities of 10 μCi to 1 mCi.

JUN 20 1984

2. This comment concerns possessing low-level survey meters for contamination surveys.

Mead Johnson presently has two low-level survey meters dedicated solely for performing contamination surveys. One system is a PUG-1 Universal Portable Survey Meter with a Pancake Geiger Probe, manufactured by Technical Associates, Canoga Park, California, Model Number PUG-1, P-11. This system is sensitive to C-14 and more energetic beta particles. The second system is a PUG-1 Universal Portable Survey Meter with a low energy gamma probe, manufactured by Technical Associates, Model Number PUG-1, PGS-3IP. This system is very sensitive to I-125. The lowest level range for each system is 0 to 0.2 mR/hr.

3. This comment concerns bioassay procedures for I-125 and H-3.

Mead Johnson has recently obtained a Thyroid Uptake System from Atomic Products Corporation, Model Number 187-115. All employees who work in a laboratory handling I-125 must submit to a weekly thyroid scan and in addition any employee using I-125 to label organic compounds must submit to a thyroid scan immediately before the experiment begins and no sooner than 6 hours and no later than 24 hours following the conclusion of the experiment. Corrective action will be taken whenever the thyroid burden exceeds 0.12 μCi.

In regards to tritium bioassays, corrective action will be taken if urinary excretion exceeds 3 μCi/L.

4. This comment concerns informing ancillary personnel about radiation hazards and appropriate precautions.

   A memorandum describing procedures to be followed by ancillary personnel has been sent to the departments concerned. (See Attachment A).

5. These comments concern our procedures for ordering, receiving, storing, using, transferring and disposing of radioactive material.

   Our procedures for ordering, receiving, storing, using, transferring and disposing of radioactive material is given in Attachment B, "Procedures for Handling Radioactive Materials".

   Additional procedures for storing radioactive materials to conform to Section 20.105 of 10 CFR Part 20 is given in Attachment C, "Radiation Safety Manual", page 14.

6. These comments concern our procedures for examining incoming packages of radioactive material.

Our procedures for handling incoming packages containing radioactive material is given in Attachment B, "Procedures for Handling Radioactive Material", Section 5, Receipt.

7. These comments concern our instructions given to all laboratory personnel working with radioactive material.

In regards to 7a:

All radioactive materials are used by or directly under the supervision of a "licensed user". It is the responsibility of the "licensed user" in each department to see that the rules and regulations governing the safe handling of radioisotopes are known and observed. This information is found in Attachment C, "Introduction", page 3.

In regards to 7b:

Our policy of radiation safety in the laboratory is found in Attachment C, "Radiation Safety", page 12.

In regards to 7c:

Our limitations and conditions for handling liquid or loose radioactive material is found in Attachment C, Tritium Monitoring and Protection, Carbon-14 Monitoring and Protection, and Iodine-125 Monitoring and Protection, pages 15-17.

In regards to 7d:

Our monitoring procedures are found in Attachment B, Section 8. Monitoring.

In regards to 7e:

Instructions concerning the movement of radioactive materials between rooms is found in Attachment C, "Radiation Safety", page 13, number 19.

In regards to 7f:

Instructions pertaining to the storage and labeling of radioactive material is given in Attachment C, "Introduction", page 3, numbers 3, 4 and 7; "Radiation Safety", page 13, number 16 and "Radioactive Material Storage", page 14; and additionally in Attachment B, Section 6. Storage.

Instructions in regard to handling contaminated articles and glassware is given in Attachment B, Section 10, Disposal and in Attachment C, Radiation Safety, page 12, numbers 9, 10 and 25.

7. (continued)

In regards to 7g:

Policy pertaining to personnel monitoring devices is given in Attachment C, Personnel Dosimetry, page 10.

It is the responsibility of the RPO to insure that dosimetry badges and rings are processed on a monthly basis.

In regards to 7h:

Instructions pertaining to the disposal of radioactive material is given in Attachment B, Section 10, Disposal.

In regards to 7i:

Instructions pertaining to records kept for the use and disposal of radioactive material is given in Attachment B, Section 6, Storage; Section 7, Use; Section 9, Transfer; and Sections 10.1 and 10.3, Disposal.

In regards to 7j:

Our policy of contamination control procedures is given in Attachment C, Radiation Safety.

8. This comment concerns instructions given to animal caretakers handling animals given radioactive material.

A memorandum describing procedures for handling animals receiving radioactive materials has been sent to the departments concerned. (See Attachment D).

9. This comment concerns safety instructions for the usage of millicurie quantities of P-32.

   A memorandum describing special safety instructions to be followed by personnel handling millicurie quantities of P-32 has been sent to the departments concerned. (See Attachment E).

Hopefully these remarks have adequately addressed your questions.

Sincerely yours,

Douglas M. Dischino

D. D. Dischino, Ph.D.
Radiation Protection Officer
Metabolism and Pharmacokinetics

/tjs
Attachments

ATTACHMENT A

BRISTOL-MYERS COMPANY
PHARMACEUTICAL RESEARCH AND DEVELOPMENT DIVISION

Memorandum

FROM D. Dischino

DATE May 29, 1984

TO See Below *

SUBJECT RADIATION PROTECTION FOR ANCILLARY PERSONNEL

*R. J. Collins
J. A. LaBudde
E. Lander
C. L. Ogden

In compliance with the rules and regulations concerning our NRC Materials License, I am supplying you with procedures to be followed by all ancillary personnel (maintenance, housekeeping and security) whose duties may require them to work in the vicinity of radioactive material.

Maintenance

Maintenance personnel may work near radioactive material or contaminated surfaces when servicing hoods or equipment.

The following procedures will be taken when servicing hoods:

1. Notify either Dr. R. Mayol or myself at least one (1) day before initiating any work.

2. There will be a radiation monitor available for use by any maintenance personnel to monitor any surface in the exhaust system prior to servicing the system.

3. Maintenance personnel should wear protective sleeve covers and gloves to prevent inadvertently rubbing against potentially contaminated surfaces.

4. Maintenance personnel should wear protective face masks to prevent inhaling potentially contaminated particulate matter.

The following procedures will be taken when servicing laboratory equipment in rooms where radioactive material is handled:

1. Maintenance personnel will ascertain from the responsible scientist that the equipment or area to be serviced is free from radioactive materials.

Security

In the event that security personnel must enter a laboratory where radioactive materials are handled, the following procedures will be followed:

1. Security personnel will not touch or move any material or containers labeled "Radioactive Material".

2. In the event of an incident (fire, water leak, explosion, etc.) in an area handling radioactive materials, the security personnel will contact the responsible scientist for that laboratory and the RPO and inform them of the situation. The scientist and RPO may then both be required to be present to assist in any corrective actions to be taken depending upon the type and severity of the situation.

Housekeeping

It is a policy of the company that members of the housekeeping staff will not touch or move any equipment, glassware, reagent and any items labeled "Radioactive Material" in the laboratory. Prior to requesting custodial service in a laboratory, the scientist requesting the service will determine that the area to be serviced is free of radioactive material.

In addition to the above, all ancillary personnel shall receive a copyof the Radiation Safety Manual and signify in writing that they have read it and will comply with its provisions.

It will be the responsibility of each supervisor to convey these procedures to their personnel and to review these procedures with them annually.

ATTACHMENT B

BRISTOL-MYERS COMPANY
PHARMACEUTICAL RESEARCH AND DEVELOPMENT DIVISION

Memorandum

FROM D. D. Dischino

DATE December 14, 1983

TO See Below *

SUBJECT PROCEDURES FOR HANDLING RADIOACTIVE MATERIAL

* M. J. Bartek
J. E. Byrne
R. R. Covington
K. E. Davis
W. T. Ellis
D. G. Gallo
R. E. Gammans
E. Gillespie
R. C. Hanson
L. D. Jost
J. A. LaBudde
R. F. Mayol
L. B. Rosenberger
H. C. Stanton
E. G. Swenson
R. D. Talbott
D. P. Taylor

In compliance with recently approved rules and regulations governing our NRC By-Product Material License, I am supplying you with a copy of our Procedures for Handling Radioactive Material. These procedures provide instructions for ordering, receiving, storing, using, transferring and disposing of radioactive material.

Effective January 3, 1984, all radioactive material received by the Company are to be recorded in the Radioisotope Log Book by the intended user of the material. A sample copy of the radioisotope log book information sheet is enclosed.

/tjs
Enclosures

RADIOISOTOPE LOG BOOK
INFORMATION SHEET

MATERIAL (NAME):

RADIOACTIVE ELEMENT:

DATE RECEIVED:

SOURCE OF MATERIAL:

LOT OR NOTEBOOK NUMBER:

SPECIFIC ACTIVITY:

TOTAL ACTIVITY:

RESULT FROM WIPE TEST (DPM):

SIGNATURE OF PERSON LOGGING DATA:

STORAGE LOCATION (FREEZER OR ROOM NUMBER):

PROCEDURES FOR HANDLING RADIOACTIVE MATERIAL

1. PURPOSE

To provide instructions for ordering, receiving, storing, using, transferring, and disposing of radioactive elements and compounds.

2. SCOPE

These procedures apply to all radioactive elements and compounds used in the Company.

3. RESPONSIBILITY

These procedures are to be followed by any and all personnel who order, receive, store, use, transfer or dispose of radioactive elements or compounds.

4. REQUISITION

4.1 Orders from outside Bristol-Myers: Evansville Site

Requests for purchase of radioactive materials are made using a "Purchase Requisition". The Radiation Protection Officer will review each requisition and ensure that our license limitations are not exceeded.

4.2 Orders for Radioactive Compounds prepared within Bristol-Myers

Requests for radiolabeled compounds or other specific compounds for drug disposition work are made by the Director of the Department via a memoranda to the appropriate group.

5. RECEIPT

5.1 Radioactive compounds or elements ordered from outside of the Evansville site are delivered directly to the designated recepient.

5.2 Within 24 hours of receipt, the package is opened and its contents inspected using the following procedure:

Monitor the outside of the package with a survey meter. Place the package on a sheet of plastic-backed absorbent paper. If the material is volatile open the package in a hood.

Wearing a pair of protective gloves, open the package, and verify that the contents conform in name, isotope and activity ordered.

Check for possible breakage or leakage.

Wipe the outside of innermost container with a 1" diameter filter paper. Count the paper in a liquid scintillation counter (if a beta emitter) or a gamma counter (if a gamma emitter).

If contamination, leakage or discrepancies in isotope or activity ordered are observed, notify the Radiation Protection Officer.

Dispose of all packaging materials in a drum for solid radioactive wastes.

5.3 All radioactive compounds or elements received by the Company are to be recorded in the Radioisotope Log Book, by the intended user of the material. The following information is to be recorded on loose sheets and are then given to the RPO for filing.

Material (name):
Radioactive element:
Date received:
Source of material:
Lot or notebook number:
Total weight of material:
Specific activity:
Total μCi:
Results from Wipe Test (DPM):
Signature of person logging data:
Storage location (freezer or room number):

5.4 Transfers of radioactive compounds from one Department to another must be authorized by Department Directors. The RPO must be notified of the transfer.

6. STORAGE

6.1 All radioactive materials are to be stored in a refrigerator under lock.

6.2 Each laboratory handling radioactive materials will be required to perform an inventory of all radioactive materials in their possession every three months. The following information must appear on the inventory:

Compound
Radioisotope
Previous Inventory
Amount Received
Amount and Method of Disposal
Current Inventory.

7. USE

Each time a radioactive material is used the following information must be recorded on an inventory card:

Amount of material removed
Amount of material remaining
Use of material
Name of person removing material
Date of removal.

8. MONITORING

8.1 Each laboratory handling radioactive materials must monitor their own work area for possible contamination. Every three months, the recommended procedure is stated below:

A 2" x 2" gauze pad is moistened with 95% ethanol and used to swab a one-square foot area of work space. The gauze pad is allowed to air dry and the amount of radioactivity present determined by appropriate means and compared with the natural background of a similar gauze pad also moistened with alcohol but not allowed to touch a working surface.

8.2 A sketch of the laboratory will be submitted with the report identifying the areas of laboratory swabbed.

8.3 If quanitites of contamination appreciably greater than background are found, the entire area should be repeatedly cleaned and monitored until the contamination is removed.

8.4 Leak testing of all Ni-63 election captive detector cells for gas chromatographic units will be performed every 6 months.

8.5 Leak testing of all FILTEC Model FT-12 fill level gauges will be performed every six months.

9. TRANSFER

9.1 Within the Evansville site

Transfer of radioactive material between groups must be authorized by the Department Directors. The Radiation Protection Officer is to be notified of the intended transfer. The transfer is to be documented in a memorandum giving the following information:

1. The material (name).
2. Lot or notebook number for compound.
3. The amount transferred.
4. The Department receiving the material.
5. The reason for the transfer.
6. The Department sending the material.
7. The date of transfer.

This information must also be entered in the Departmental Radioisotope Log Book.

9.2 Outside of the Evansville site

Transfers of radioactive elements or compounds outside of the Evansville site must be handled by the Radiation Protection Officer.

10. DISPOSAL

10.1 Instructions for the packaging of radioactive waste can be found in Appendix 1.

10.2 Instructions for the temporary storage of packaged radioactive waste can be found in Appendix 2.

10.3 Instructions for the transfer of packaged radioactive waste to a waste collector for transportation to a licensed land disposal facility. Can be found in Appendix 3.

11. QUALITY CONTROL

11.1 It will be the responsibility of the RPO to insure compliance with the above procedures.

AUTHORIZED BY: J. A. Brown

EFFECTIVE DATE: Jan. 6, 1984

APPENDIX 1

PACKAGING INSTRUCTIONS FOR RADIOACTIVE WASTE DISPOSAL

A. Responsible Personnel

Each NRC licensed user of radioisotopes is responsible for initial disposition of the radioactive waste resulting from his work in accord with the procedures described in section B. Storage, transfer and shipment of radioactive waste from the company is the responsibility of the Radiation Protection Officer (RPO) and the Hazardous Waste Manager.

B. Aqueous Solutions and Wastes Soluble or Readily Dispersible in Water

Liquid radioactive waste containing 1 millicurie or less of either H-3, or C-14 are disposed of in the sanitary sewage system provided this does not conflict with regulations for non-radioactive waste disposal. The RPO is consulted prior to disposal of larger quantities of either H-3 or C-14 and all other radionuclides.

C. Liquid Radioactive Waste Containing More Than 1 Millicurie of H-3 or C-14

Disposal is in 1 liter polyethylene bottles containing vermiculite.

1. Obtain a 1 liter polyethylene bottle with a secure cap and label bottle with a "Caution - Radioactive Material" label.

2. Fill bottle half-full with vermiculite.

3. Add the radioactive waste until the vermiculite is saturated.

4. Fill the bottle with vermiculite and close with cap.

5. Bottles will be placed in a 30 gallon steel drum containing 4 inches of vermiculite at the bottom of the drum. Space between bottles will be filled with vermiculite.

6. When the drum is full, it is sealed and centered inside of a 55 gallon metal drum. Vermiculite is added to fill the space between the drums and then the 55 gallon drum is sealed by ring, bolt and locknut -- gasket must be used.

7. The drum is then clearly labeled as to its contents, type and quantity of radionuclide, and labeled as a class A waste. (See Attachment.)

D. Dry Waste Consisting of Glass, Plastic, Paper, Inert Chemicals or Metal

1. All solid radioactive waste generated in Building 106 will be compacted prior to disposal. The radioactive trash compactors are located outside of rooms 1015 and 2225. Radioactive waste generated elsewhere will not be compacted prior to disposal.

2. Disposal will be in a DOT Specification 17H, 55 gallon metal drum.

3. Line drum with a polyethylene liner with a minimum thickness of 4 mil. Add 3 inches of vermiculite in the bottom of the liner.

4. Place solid (compacted) waste material in drum liner. When the drum is full, fold over the top of the liner and tape closed.

5. Secure lid on drum by ring, bolt and locknut -- gasket must be used.

6. The drum is then labeled as described in section C. 7.

E. Scintillation Vials

1. Disposal will be in DOT Specification 17H, 55 gallon metal drum.

2. Line the metal drum with a polyethylene liner with a minimum thickness of 4 mil.

3. Place 6 inches of vermiculite in the bottom of the liner. Place another liner in the drum.

4. Fill inner bag of vials. After every 300 vials place 2 inches of vermiculite over the vials. Continue this process until the level of the vials is 6 inches from the top.

5. Fill the liner with 4 inches of vermiculite and secure the liner with tape.

6. Secure lid on drum by ring, bolt, and locknut -- gasket must be used.

7. The drum will then be labeled as follows:

Flammable Waste

Contents:
50% Toluene
45% Xylene
5% Phenethylamine

PACKAGING INSTRUCTIONS FOR RADIOACTIVE WASTE DISPOSAL
(continued)

F. Animal Carcasses

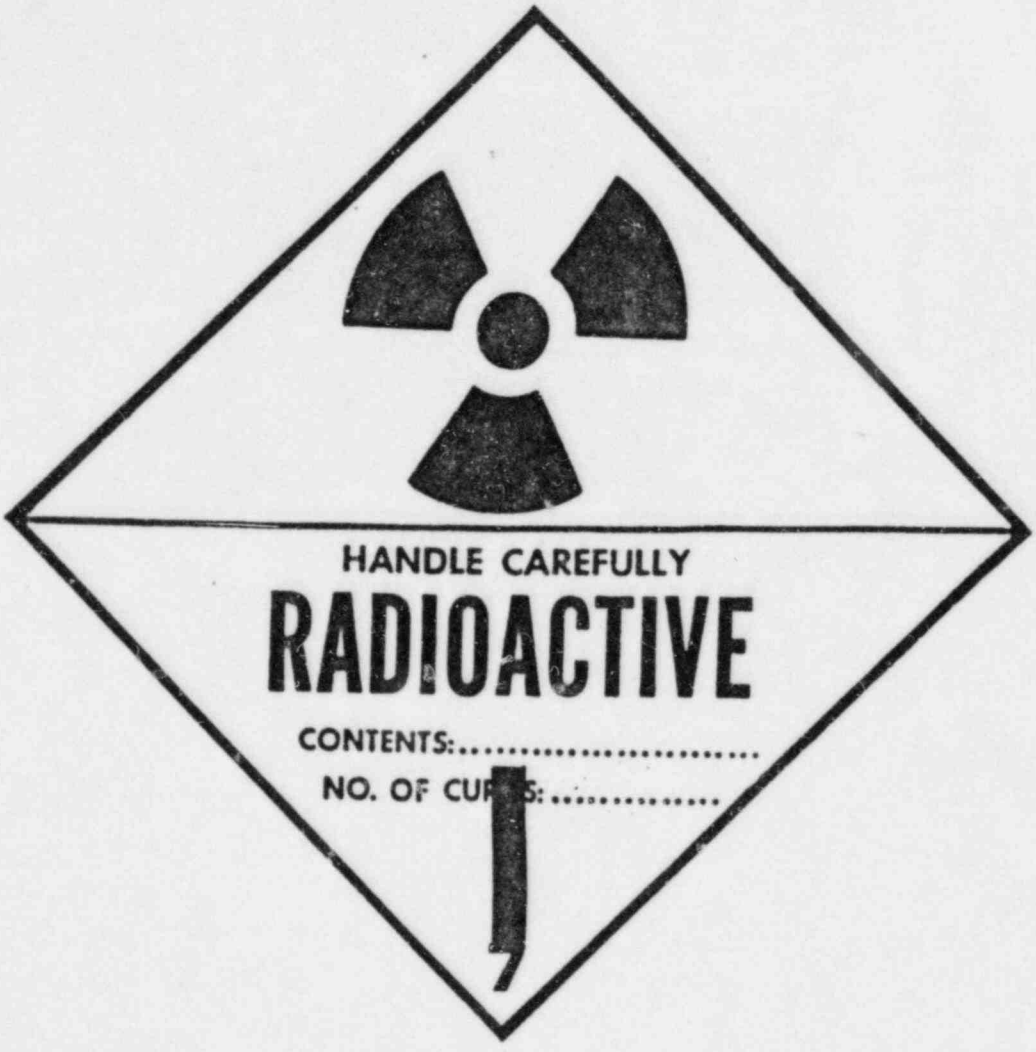
Disposal is by incineration providing that there is no more than 0.05 microcuries of H-3 or C-14 per gram of animal tissue averaged over the weight of the entire animal. All animal carcasses are doubl bagged in plastic trash liners and stored in the freezer in Build. 106, Room 1206 prior to incineration. Consult the RPO for disposal of animal carcasses containing all other radionuclides.

G. Corrosive or Highly Reactive Chemical Waste

Certain very hazardous materials may require neutralization or conversion to a less reactive form prior to disposal. Suitable procedures for disposal of this type of material are arranged in consultation with the RPO. Presently no such materials are being used.

H. Records

Individual licensed users keep a record of their radioactive waste disposal with an account of the type and quantity of isotope being disposed of and route of disposal. This record is submitted to the RPO every three months. The RPO keeps a record of total waste disposal by the Company on a quarterly and yearly basis.


HANDLE CAREFULLY
RADIOACTIVE
CONTENTS:.....
NO. OF CU S:.....
7

APPENDIX 2

INSTRUCTIONS FOR THE TEMPORARY STORAGE OF PACKAGED RADIOACTIVE WASTE

1. The RPO will certify that each drum of packaged radioactive waste has been properly classified, described, packaged, marked, labeled and in proper condition for transportation by signing his name and date on the top lid of each container.

2. Drums containing de-regulated scintillation vials will be stored in the hazardous waste storage area located at the MJ Park.

3. Drums containing all other forms of radioactive waste will be stored in the basement of Building 16.

4. It will be the responsibility of the hazardous waste manager to insure that the drums remain undamaged while in storage.

LABU/JA/

APPENDIX 3

INSTRUCTIONS FOR THE TRANSFER OF PACKAGED RADIOACTIVE WASTE TO A WASTE COLLECTOR FOR TRANSPORTATION TO A LICENSED LAND DISPOSAL FACILITY

1. Each shipment of radioactive waste to a licensed land disposal facility must be accompanied by a shipment manifest.

2. The shipment manifest will contain the following information:

   a. The name, address and telephone number of the name and EPA hazardous waste identification of the person transporting the waste to the land disposal facility.

   b. A physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity and the principal chemical form. See Appendix A.

3. It will be the responsibility of the RPO to complete and sign this manifest.

4. The waste collector will receive at the time of collection one complete copy of the manifest and a statement from the RPO describing how the material was packaged.

5. The waste collector will then acknowledge in writing receipt of the packaged radioactive waste.

6. The hazardous waste manager will keep one copy of the manifest and documentation of acknowledgement until disposition is authorized by the NRC.

7. The RPO will contact the NRC prior to each shipment of radioactive waste to insure that the waste collector has remained in good standing with the NRC since the last shipment of radioactive waste.

Date: _____

№ 42670

RADIOACTIVE WASTE SHIPMENT RECORD

ADCO SERVICES, INC.

P.O. BOX 35 TINLEY PARK, IL 60477

(312) 429-1660

APPENDIX A

TOTAL QUANTITY	PROPER SHIPPING NAME & HAZARD CLASS (PER 49 CFR 172.101)	TOTAL WEIGHT IN POUNDS
	Radioactive Device, N. O. S. – Radioactive Material	
	Radioactive Material, Fissile, N. O. S. – Radioactive Material	
	Radioactive Material, Low Specific Activity, N. O. S. – Radioactive Material	
	Radioactive Material, N. O. S. – Radioactive Material	
	Radioactive Material, Limited Quantity, N. O. S. – Radioactive Material	
	Other (Specify) – Radioactive Material	

(1) Item No.	(2) Cubic Feet	(3) Weight (Pounds)	(4) Physical Form	(5) Chemical Form	(6) Radionuclide	(7) Special Nuclear Material (Grams)	(8) Source Material (Kilograms)	(9) Activity ☐ Curies ☐ Millicuries	(10) Radiation Levels MR/HR Surface	(10) 3 Feet	(11) Transport Group	(12) Transport Index	(13) Label	(14) Fissile Class	(15) Type of Container
													Radioactive –		
													Radioactive –		
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			TOTALS												

DISCLAIMER: Upon acceptance of shipment, the materials therein become the sole property of ADCO SERVICES, INC.

THIS IS TO CERTIFY THAT THE ABOVE-NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED AND LABELED AND ARE IN PROPER CONDITION FOR TRANSPORTATION ACCORDING TO APPLICABLE REGULATIONS OF THE DEPARTMENT OF TRANSPORTATION AND ADCO SERVICES, INC.

_____ _____

Authorized Signature *Title*

ADCO SERVICES AGENT

Signature: _____

Date: _____