

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. T.P.S. Incorporated	3. License Number	13-26086-02
2. 10424 Middle Mt. Vernon Road Mt. Vernon, IN 47620	4. Expiration Date	November 30, 2001
	5. Docket or Reference No.	030-34237
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Carbon-14	A. Non-volatile chemical compounds	A. 50 millicuries
B. Hydrogen-3	B. Non-volatile chemical compounds	B. 100 millicuries
C. Sulfur-35	C. Non-volatile chemical compounds	C. 50 millicuries
D. Iodine-125	D. Labeled proteins or biochemicals	D. 5 millicuries
E. Iodine-131	E. Labeled proteins or biochemicals	E. 5 millicuries

9. Authorized Use:

A. through E. For use in biology experiments in laboratory animals.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 10424 Middle Mt. Vernon Road, Mt. Vernon, Indiana.
11. Licensed material shall be used by, or under the supervision of, John A. LaBudde, Ph.D.
12. The Radiation Safety Officer for this license is John A. LaBudde, Ph.D.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-26086-02

Docket or Reference Number

030-34237

13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:
- A. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
 - B. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.
17. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated September 5, 1996 (as resubmitted with letter dated October 11, 1996); and
 - B. Letters dated October 11, 1996 and October 24, 1996 (with enclosures).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 30, 1996

By

Loren J. Hester
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

R8

Program Code: _____
Status Code: 3
Fee Category: _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Req'd: _____
.....T.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: T. P. S. INCORPORATED
Received Date: 960906
Docket No: 3034237
Control No.: 301810
License No.: _____
Action Type: New License

2. FEE ATTACHED

Amount: 1500
Check No.: 24613

3. COMMENTS

Signed S. Hersey
Date 9-9-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: 3M \$1500

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License ✓

3. OTHER

Signed SC
Date 9/16/96

SEP 19 1996

Log	<u>APP 5 III</u>
Remitter	_____
Check No.	<u>24613</u>
Amount	<u>\$1500</u>
Fee Category	<u>3M</u>
Type of Fee	<u>APP</u>
Date Check Rec'd	<u>9/12/96</u>
Date Completed	<u>9/16/96</u>
By:	<u>SC</u>

1996 SEP 12 PM 3:53

(7-96)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-8 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-6064

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 JURISDICTIONS.

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

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

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

T.P.S., INC.
10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

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

10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John A. LaBudde

TELEPHONE NUMBER
(812) 985-5900

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3M

AMOUNT
ENCLOSED \$ 1,500.00

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, 36, 39 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

J.A. Botta, Jr., DVM, PhD., Scientific Director

J.A. Botta, Jr.

9-5-96

FOR NRC USE ONLY

TYPE OF FEE FEE LOG FEE CATEGORY AMOUNT RECEIVED CHECK NUMBER COMMENTS

\$

APPROVED BY

DATE

RECEIVED

SEP 06 1996

301810



September 4, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Gentlemen:

Enclosed please find our application for a new NRC Byproduct Material License and a check for \$1,500.00 to cover the license application fee. Any correspondence concerning this application should be directed to me.

Sincerely,

A handwritten signature in dark ink, appearing to read "J. A. Botta, Jr.", is written over a light-colored background.

J. A. Botta, Jr., D.V.M., Ph.D.
Scientific Director
T.P.S., Inc.

JAB:bjs

Enclosures

RECEIVED
SEP 06 1996
REGION III

SEP 06 1996

APPLICATION FOR MATERIAL LICENSE

5. RADIOACTIVE MATERIAL

Element-Mass Number	Chemical/Physical Form	Maximum Amount
a. Carbon-14	Non-volatile chemical compounds	50 mCi
b. Hydrogen-3	Non-volatile chemical compounds	100 mCi
c. Sulfur-35	Non-volatile chemical compounds	50 mCi
d. Iodine-125	Labeled proteins or biochemicals	5 mCi
e. Iodine-131	Labeled proteins or biochemicals	5 mCi

6. PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

Biology experiments in laboratory animals.

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

John A. LaBudde will be the Radiation Protection Officer.

Training and experience of John A. LaBudde, Ph.D. in the handling and use of radioactive isotopes.

TRAINING

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>
Disposal methods. "Hot lab" work and clean-up procedures. Routine sample count- ing and handling.	University of Wisconsin Madison, Wisconsin Dept. of Oncology	1956-59 - While a Ph.D. graduate student.

APPLICATION FOR MATERIAL LICENSE (cont'd)

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (cont'd)

<u>Isotope</u>	<u>Maximum Amt.</u>	<u>Where Experience Was Gained</u>	<u>Duration</u>	<u>Type of Experience</u>
Carbon-14	100 mCi	Dept. of Oncology University of Wisconsin Madison, WI	1956-58	Metabolism studies.
		Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1959-87	Radio-Chemical Synthesis Metabolism studies.
Hydrogen-3	1 Ci	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1959-87	Radio-Chemical Synthesis Metabolism studies.
Sulfur-35	100 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.
Iodine-125	30 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.
Iodine-131	30 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.

The duties of the Radiation Protection Officer will be as follows:

- Ensure that radioactive material will be used by or under the direct supervision of individuals specifically listed on the license.
- Ensure that, where appropriate, all personnel wear monitoring equipment and protective clothing when working with radioactive materials.
- Ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.
- Perform routine inspections of all laboratories in which radioactive materials are used or stored.

APPLICATION FOR MATERIAL LICENSE (cont'd)

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (cont'd)

- e. Ensure that the terms and conditions of the Byproduct Material License are met and that required records are maintained.
- f. Immediately halt any activity judged to be a threat to health, safety, the environment, or a violation of the conditions of the Byproduct Material License or the regulations.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Each individual will, initially and then annually, be instructed in radiation safety. This will include:

- a. The nature of radiation and the hazards that may be encountered.
- b. The biological effects of radiation.
- c. The principles and techniques of radiation protection.

Individuals will be instructed in the handling and use of the radioactive materials with which they are working.

Experiments will be performed in accord with standard operating procedures for safe handling of radioactive materials as described in Appendix I.

9. FACILITIES AND EQUIPMENT

Radioisotope experiments will be performed in Bldg. 101, Rooms A and B and Clinical Preparation area as shown in Appendix II.

This building is equipped with water and electric outlets. Bench areas are formica and sinks are stainless steel.

Radioisotopes will be stored in locked cabinets or refrigerators. Strong beta emitters will be kept in plexiglass containers. Appropriate shielding such as lead bricks and handling equipment such as remote pipetting device will be available where their use is indicated.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM

A radiation protection program will be maintained in conformance with the regulations in Title 10, Part 20 of the Code of Federal Regulations. This program will include the following:

- a. Prior to the use of radioisotopes at T.P.S., Inc., employees working with the radioisotopes, as well as personnel who may work in the area in which radioisotopes will be present, will be properly instructed with respect to safety problems associated with exposure to the radioactive materials and precautions to be taken. Written laboratory safety standards entitled "Safety Rules and Guidelines for Handling, Storage and Disposal of Radioisotopes" (Appendix I) will be distributed to employees involved in radioisotope work. Special instructions will be provided to animal caretakers as outlined in Section F of the "Safety Rules and Guidelines".
- b. Copies of the regulations governing protection against radiation and copies of the Byproduct Material License will be immediately available.
- c. Form NRC-3 will be posted in all areas where work is conducted with radioactive materials.
- d. Caution signs will be appropriately placed in radiation areas and where radioactive materials are stored.
- e. Containers containing radioactive materials will be appropriately labeled.
- f. Film Badges - all persons who may be exposed to radioactive material will be required to wear film badges. Film badges will be supplied and monitored monthly by Landauer, Glenwood, IL 60425.
- g. Survey Program - Laboratory work areas will be monitored on a monthly basis in accord with the instructions provided in Appendix I. Whenever experiments are performed using a strong beta or gamma emitter, a survey meter will be used to monitor the work area during and after the experiment. The following records will be maintained for both area and surface contamination surveys.
 - 1) The date of the survey,
 - 2) The name of the individual conducting the survey,
 - 3) The instrumentation used to evaluate the radiation and/or contamination levels and;
 - 4) Corrective actions taken if decontamination action levels are exceeded.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

- h. Records Management Program - Record keeping and review will be the responsibility of the Radiation Protection Officer. The following records will be retained.
 - 1) Radioisotope survey records including monthly wipe test results and monthly film badge results.
 - 2) Radioactive materials inventories including receipts, current inventory and disposal.
 - 3) Copies of the Safety Rules and Guidelines for Handling Radioisotopes, copies of the NRC license, amendments to the license, and correspondence relating to radioisotope usage.
- i. Management of Radiation Accidents
 - 1) Ingestion: Persons swallowing radioactive solutions will be treated as for poisoning. Blood and urine samples may be taken in order to assess the degree of exposure.
 - 2) Surface Contamination: Contaminated clothing should be disposed of as radioactive waste. Contamination on the skin should be removed immediately.
 - 3) Minor Injuries: Persons cut by glass, injured by hypodermic needles, etc. under circumstances in which radioactive material may have contaminated the wound, should wash the injured part under a stream of water immediately. Following initial first aid action, medical attention will be obtained promptly. Arrangements should be made to take a surface count.
 - 4) All accidents resulting in the exposure of individuals to radioactive materials must be reported to the Radiation Protection Officer.
- j. The following radiation detection instrument will be used:

Survey meter - Ludlum Model 3 Survey Meter with Model 44-21 Beta/Gamma Sandwich Detector. Efficiency: 16% for C-14, 38% for I-125.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

k. Calibration

Survey meter - a battery test of the survey meter will be performed prior to each usage. A complete calibration will be performed every 6 months by the manufacturer:

Ludlum Measurements, Inc.
501 Oak Street
P. O. Box 810
Sweetwater, TX 79556
NRC License No. 4-1963

- l. It is not planned or expected that experiments will be performed with either tritium, iodine-131 or iodine-125 which will exceed levels which, according to NRC guidelines, require that a bioassay program for these radionuclides be established. If such experiments are planned in the future, appropriate bioassay procedures will be submitted to the NRC prior to initiation of the experiments.

m. Animal Experiments

- 1) All experiments will be performed under the supervision of the RPO.
- 2) Animals will be brought into the radioisotope laboratory prior to administration of radioisotopes.
- 3) After administration of a radioisotope to an animal, the animal will be housed in a metabolism cage for the collection of urine and feces until the animal is either sacrificed or testing has demonstrated that the animal is essentially free of radioactivity.
- 4) Waste from animals to which radioisotopes have been administered will be assumed to be radioactive and will be handled as such. Disposal of animal waste will be performed in accordance with directions from the RPO.
- 5) Following termination of an experiment, carcasses from animals that have been sacrificed will be certified by the RPO as being either a) Non-radioactive ($< 0.05 \mu\text{Ci/G}$) in which case they can be disposed of as non-radioactive waste or b) Radioactive, in which case they will be disposed of by a contract waste disposal company.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

m. Animal Experiments (cont'd)

- 6) Prior to removal of cages used in radioisotope experiments from the radioisotope laboratory, solid material will be removed and disposed of as radioactive waste, and the cages will be rinsed with water to remove soluble radioactivity. The cages can then be submitted to the usual animal cage washing procedures.

11. WASTE DISPOSAL

All materials will be disposed of in accordance with regulations set forth in Sections 20.106 (a), 20.302, 20.303, 20.304 and 20.305 of the Code of Federal Regulations. Specifically, most of the soluble and water-dispersible wastes will be disposed of through a sanitary sewer system under conditions authorized and will not exceed the limits described for such disposal.

All solid and liquid waste matter not released into the sewer system will be disposed of by a licensed, commercial, radioactive waste disposal company. We will be utilizing the services of Adco Services, Inc., Tinley Park, Illinois. Waste will be packaged in conformance with "Radioactive Waste Packaging Instructions" provided by Adco Services, Inc.

APPENDIX I

**T.P.S., Inc. Standard Operating Procedure of
Safety Rules and Guidelines for Handling,
Storage, and Disposal of Radioisotopes**

T.P.S., INC. PROCEDURES

PAGE 1 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>R. W. Lulu</i>	<i>9/5/96</i>	<i>M. J. Burt</i>	<i>9/5/96</i>	<i>J. A. Bost</i>	<i>9-5-96</i>

TITLE: Safety Rules and Guidelines for Handling, Storage, and Disposal of Radioisotopes

PURPOSE: To provide safety rules and guidelines for handling, storage and disposal of radioisotopes.

SCOPE: Applies to the training of new employees or those with no prior radiation experience by personnel of T.P.S., Inc. for the evaluation of animal studies.

RESPONSIBILITY:

1. The Radiation Protection Officer (RPO) shall maintain that this procedure is used and followed for handling, storage, and disposal of radioisotopes.
2. The Quality Assurance Unit shall review this procedure.
3. It shall be the responsibility of the Scientific Director to evaluate and update this procedure, as required.

PROCEDURES:

- A. Training of New Employees or Those With No Prior Radiation Experience

It is the responsibility of the RPO to ensure that all employees working with radioisotopes be given instruction pertaining to the safety problems associated with exposure to sources of ionizing radiation and the precautions and procedures to be taken to minimize such exposure. The employee must demonstrate understanding of the nature of the radiation hazards to be encountered, the biological effects (somatic and genetic) of radiation and the principles and techniques of radiation protection.

T.P.S., INC. PROCEDURES

PAGE 2 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>GH Wheeler</i>	<i>9/5/96</i>	<i>M Brundage</i>	<i>9/5/96</i>	<i>J A Batley</i>	<i>9-5-96</i>

B. Individual User Responsibilities

Each employee working with radioisotopes will:

1. Receive a copy of these guidelines, read it and signify in writing their intent to comply with its provisions.
2. Provide the RPO with a complete employment history involving work with sources of ionizing radiation.
3. Promptly notify the RPO of any accidental inhalation, ingestion, or injury involving radioactive material and carry out the recommended corrective actions.
4. Promptly notify the RPO of any accidental release of radioactive material and carry out the recommended corrective actions.
5. Female employees are encouraged to notify the RPO of any childbearing intention or pregnancy so that risk to the fetus from exposure or potential exposure to sources of ionizing radiation in the laboratory may be minimized.

C. General

1. Radioactive material is to be used only under the direct supervision of a "licensed user".
2. It is the responsibility of the "licensed user" to see that the rules and regulations governing the safe handling of radioisotopes are known and observed.
3. Each area where radioisotopes are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and words "Caution - Radiation Area". A sign bearing the radiation caution symbol and words "Caution - Radioactive Materials" will also be posted in areas where radioactive materials are stored. All individuals working in or frequenting an area where

T.P.S., INC. PROCEDURES

PAGE 3 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>R. Wheeler</i>	<i>9/5/96</i>	<i>M. G. Borden</i>	<i>9/5/96</i>	<i>J. A. Borden</i>	<i>9-5-96</i>

radioactive materials are stored or handled shall be instructed in the safety problems associated with exposure to such materials.

4. All containers used for radioisotopes must be marked with a magenta on yellow radioactive material label identifying the radioactive contents.
5. Form NRC-3, "Notice to Employees", shall be conspicuously posted in a sufficient number of places in the laboratories so that employees may observe a copy on the way to or from the laboratories.
6. A copy of the regulations, license, and operating procedures regarding the use of radioisotopes will be available for employees' examination upon request.
7. All licensed material must be kept under lock and key to prevent unauthorized removal from its place of storage.
8. The rules contained herein are intended as general guidelines and may not cover all situations or radioisotopes. Any questions concerning their application or the handling of radioactive material should be referred to the Radiation Protection Officer.
9. Each licensed user shall post in his or her laboratory a copy of the instructions for packaging radioactive waste.

D. Receipt of Radioactive Materials

1. The RPO will review information on incoming radioactive material and ensure that our license limitations are not exceeded.
2. Radioactive materials received from outside sources are delivered directly to the RPO.

T.P.S., INC. PROCEDURES

PAGE 4 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>L. L. L. L.</i>	<i>9/5/96</i>	<i>M. B. B. B.</i>	<i>9/5/96</i>	<i>J. B. B. B.</i>	<i>9-5-96</i>

3. Within 24 hours of receipt, the package containing the radioactive material 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 the innermost container with a 1" diameter filter paper. Count the paper in a liquid scintillation counter. Dispose of all packaging materials as solid radioactive waste.

4. The following information on all radioactive materials received are to be recorded in a "Radioisotope Log Book" by the RPO.

Material (Name of Compound):
Radioisotope:
Date Received:
Source of Material:
Weight of Material:
Specific Activity:
Total Microcuries:
Results from Wipe Test:
Storage Location:

E. Handling of Radioactive Materials

Most of the radioisotopes used are weak B-emitters (3H,14C) and therefore need no additional shielding than their glass container. The major radiation hazard of these radioisotopes results from their accidental ingestion. Therefore, the following rules and procedures will be followed by all personnel handling radioactivity.

T.P.S., INC. PROCEDURES

PAGE 5 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>Gr. Lecker</i>	<i>9/5/96</i>	<i>M. Boudin</i>	<i>9/5/96</i>	<i>J. Boudin</i>	<i>9-5-96</i>

1. Do not smoke, eat, drink or apply make-up in any radiologically controlled area.
2. Wear appropriate personnel dosimetry devices and protective clothing when in a radiologically controlled area.
3. Whenever possible, wear protective gloves when handling radioactive materials. Refrain from touching exposed surfaces of skin, especially of the face, while wearing protective gloves. One should also avoid touching door knobs, drawer and cabinet handles and the telephone while wearing protective gloves.
4. Pipette radioactive solutions only by means of mechanical pipetters. Never pipette radioactive solutions by mouth.
5. Use syringes and pipettes to transfer radioactive solutions.
6. Work with plastic-backed absorbent matting beneath the radioactive materials.
7. Work in a shallow tray lined with plastic-backed absorbent matting when working with more than 10 mL of radioactive material in solution.
8. Keep the laboratory neat and clean. Radioactive material work areas should be free of equipment and materials not required for the immediate procedure.
9. Keep clean equipment close at hand or on one side of the work area. As items get used or become contaminated, place them on the other side of the work area or in a disposal container.
10. Change protective gloves before going from contaminated items to clean items.

T.P.S., INC. PROCEDURES

PAGE 6 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>H. W. Linder</i>	<i>9/5/96</i>	<i>M. J. Brundage</i>	<i>9/5/96</i>	<i>R. B. Boring</i>	<i>9-5-96</i>

11. Have an appropriate survey meter handy and turned ON before beginning the procedure. This will enable you to check hands and equipment during and at the end of the procedure. Always check the response of the survey meter before commencing work.
12. Use appropriate shielding. This is an area where consultation with the RPO would be advisable.
13. Label all items to be saved which are radioactive. The label shall contain the radioactive material symbol and the name of the isotope.
14. Wash hands and forearms thoroughly at the conclusion of the radioisotope procedure after first checking them with the survey meter for evidence of contamination.

Note: If contamination of the hand or forearm is found then, without touching anything, notify the RPO at once. After washing hands and forearms survey the work area, floor, your shoes, face, clothing and the clean equipment to be saved from the procedure. Replace any plastic-backed absorbent matting used in the procedure. The absorbent matting must be maintained in a clean condition.

15. Notify the RPO of any loss, spillage, damage or unusual occurrence involving radioactive material.
16. Transport radioactive materials between laboratories or from the laboratory to the waste disposal area in closed, protected containers.
17. Wear eye protection when working with millicurie quantities of unsealed sources of very energetic beta emitters.
18. Perform work with radioactive materials only in approved laboratories for which you are authorized.

T.P.S., INC.
PROCEDURES

PAGE 7 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>G. Wheeler</i>	<i>9/5/96</i>	<i>M. Bando</i>	<i>9/5/96</i>	<i>J. Bando</i>	<i>9-5-96</i>

F. Experiments in which Radioisotopes are Used in Animals

1. All experiments will be performed under the supervision of the RPO.
2. Animals will be brought into the radioisotope laboratory prior to administration of radioisotopes.
3. After administration of a radioisotope to an animal, the animal will be housed in a metabolism cage for the collection of urine and feces until the animal is either sacrificed or testing has demonstrated that the animal is essentially free of radioactivity.
4. Waste from animals to which radioisotopes have been administered will be assumed to be radioactive and will be handled as such. Disposal of animal waste will be performed in accordance with directions from the RPO.
5. Following termination of an experiment, carcasses from animals that have been sacrificed will be certified by the RPO as being either a) Non-radioactive ($<0.05 \mu\text{Ci/g}$) in which case they can be disposed of as non-radioactive waste or b) Radioactive, in which case they will be disposed of by a contract waste disposal company.
6. Prior to removal of cages used in radioisotope experiments from the radioisotope laboratory, solid material will be removed and disposed of as radioactive waste, and the cages will be rinsed with water to remove soluble radioactivity. The cages can then be submitted to the usual animal cage washing procedures.

G. Radioactive Material Storage

Radioactive materials will be stored according to the following guidelines:

T.P.S., INC. PROCEDURES

PAGE 8 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>G. Wheeler</i>	<i>9/5/96</i>	<i>M. J. Boudin</i>	<i>9/5/96</i>	<i>J. B. Boudin</i>	<i>9-5-96</i>

1. All radiation sources shall be secured against unauthorized removal from their places of storage or use. Radioactive material shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents. Radioactive material in storage shall be provided with reasonable protection against loss, leakage or dispersion by fire effects or by water, hose streams or other means used to fight fire.
2. Strong beta emitters will be kept in plexiglass containers.
3. Shielding for H-3, C-14 and S-35 other than their storage container is not necessary.
4. The amount of shielding placed around stored radioactive materials shall be sufficient to reduce the dose rate at all outer surfaces to less than 5 mrem/hr.

H. Radioactive Materials Inventory

1. An inventory of all radioactive materials will be performed every three months. The following information will appear on the inventory:

Material (Name of Compound)
Radioisotope
Previous Inventory
Amount Received
Amount and Method of Disposal
Current Inventory

2. A card file of radioactive materials will be maintained and each time a radioactive material is used, the following information will be recorded on an inventory card:

T.P.S., INC. PROCEDURES

PAGE 9 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

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SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>G. Leuler</i>	<i>9/5/96</i>	<i>M. Gaudoli</i>	<i>9/5/96</i>	<i>J. Abate</i>	<i>9-5-96</i>

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

I. Monitoring

1. Each laboratory in which radioactive materials are handled must be monitored for possible contamination monthly. The following procedure will be used:

A 2" x 2" gauze pad is moistened with ethanol and used to swab a 100 cm² area of work space. The gauze pad is placed in a liquid scintillation vial and the amount of radioactivity present determined by liquid scintillation counting and compared with the natural background of a control gauze pad also moistened with alcohol. Determination of wipe test sample radioactivity will be performed at GFI Pharmaceutical Services, Inc., Evansville, Indiana.

2. The results of the wipe tests, including a sketch of the laboratory identifying the areas monitored, will be submitted to the RPO.
3. If quantities of contamination appreciably greater than 200 dpm/cm² are found, the entire area should be repeatedly cleaned and monitored until the contamination is removed.
4. Tritium monitoring and protection - Tritium disintegrates to He-3 with the emission of an 18 keV electron. The external hazard from tritium in the elemental form (HT or T₂) is small because of the low energy of the beta particles emitted. The internal hazard from tri-tium is reduced by the fact that absorption is less than 0.1% by the lung tissue and negligible through the skin.

T.P.S., INC. PROCEDURES

PAGE 10 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

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Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>Gruecker</i>	<i>9/5/96</i>	<i>M. Bandini</i>	<i>9/5/96</i>	<i>J. Battin</i>	<i>7-5-96</i>

The oxides of tritium (HTO and T₂O), however, are readily absorbed into the body and become uniformly distributed throughout the body fluids within 90 minutes. Almost 100% of tritium water vapor entering the lungs is absorbed and the oxides are absorbed directly through the intact skin as well. Since varying amounts of tritium oxide are associated with the release of any form of tritium, precautions should be taken for controlling exposure to tritium oxide when working with tritium in any form.

Tritium must be handled and stored only in well-ventilated areas under carefully controlled conditions. The use of metal systems is recommended for tritium work to reduce the probability of breakage and because tritium readily diffuses through stopcock grease. It is strongly recommended that all tritium work be done in a hood or glove box equipped with an exhaust system.

All equipment which has come in contact with tritiated water vapor will retain some of the tritium and should be considered contaminated. Persons working with tritiated material during a prolonged procedure must change their gloves hourly in order to avoid having the oxide diffuse through the gloves to the skin.

Air monitoring and urinalysis may be necessary for employees handling millicuric quantities of tritium.

H-3 can be monitored via liquid scintillation counting.

5. Carbon-14 Monitoring and Protection

Carbon-14 decays to N-14 with emission of an 156 KeV electron.

The primary health hazard from C-14 results from its accidental ingestion. Therefore proper laboratory technique is essential.

T.P.S., INC. PROCEDURES

PAGE 11 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>G. L. L. L.</i>	<i>9/5/96</i>	<i>M. J. B. L. L.</i>	<i>9/5/96</i>	<i>J. A. B. L. L.</i>	<i>9-5-96</i>

C-14 can be monitored via liquid scintillation counting or a survey meter equipped with a thin end window G-M tube.

J. Management of Radiation Accidents

1. Ingestion: Persons swallowing radioactive solutions will be treated as for poisoning. Blood and urine samples may be taken in order to assess the degree of exposure.
2. Surface Contamination: Contaminated clothing shall be disposed of as radioactive waste. Contamination on the skin must be removed immediately.

When the hand is contaminated with a small spot of high specific activity, it is better not to wash the entire hand as this unnecessarily spreads the contamination. Such spots are removed by washing the affected part with cotton applicators. A dry cotton applicator should be used initially followed by washing with applicators moistened in water and/or detergent. Washing with organic solvents should be avoided.

3. Minor Injuries: Persons cut by glass, injured by hypodermic needles, etc., under circumstances in which radioactive material may have contaminated the wound, should wash the injured part under a stream of water immediately. A restrictive bandage may have to be applied if the material is extremely toxic.

Following this initial first aid action, medical attention must be sought promptly. Arrangements will be made immediately to take a surface count.

4. All accidents resulting in the exposure of individuals to radioactive materials must be reported to the RPO.

T.P.S., INC. PROCEDURES

PAGE 12 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

REFERENCE NO. 420.900

SUPERSEDES: January 18, 1993

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>G. Wheeler</i>	<i>9/5/96</i>	<i>M. Bandoli</i>	<i>9/5/96</i>	<i>J. Battin</i>	<i>9-5-96</i>

K. Radioactive Waste Storage and Disposal

Radioactive waste of the following types may be generated:

1. Uncompacted Dry Solid Waste is defined as containing less than 0.5% by volume of free standing liquids. The chemical form of this waste must be paper, plastic, or glass in nature, or be in a chemical form which can be processed through volume reduction techniques.

Waste containing biological, pathogenic, or infectious material (syringes, test tubes, animal bedding and excreta, etc.) will be packaged as biological material (see Section 6 below). This material will be packaged in steel drums for shipment from the company as follows:

Place one 4 mil plastic liner inside empty drum. Drape top portion of bag over top edge of drum to prevent contaminating the outside. It is recommended that one inch of approved absorbent be placed in the bottom of the drum to absorb any residual liquids present. When drum is full, seal the liner with tape and tuck into drum. Close lid and install locking ring.

2. Deregulated Scintillation Vials contain only H-3 and/or C-14 with a maximum concentration of 0.05 $\mu\text{Ci/mL}$.

These vials will be packaged in steel drums for shipment from the company as follows:

Place a 4 mil plastic liner in the drum. Place 4-6 inches of absorbent in the bottom of the lined drum. Place a second 4 mil plastic liner in the drum. Drape the top portion of the liner over the top edge of the drum. Add scintillation vials to within 3 inches from the top. Do not add absorbent to inner liner with the vials. Close and seal inner liner and outer liner, close drum and install locking ring.

T.P.S., INC. PROCEDURES

PAGE 13 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

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Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>Gr Wheeler</i>	<i>9/5/96</i>	<i>M Bandell</i>	<i>9/5/96</i>	<i>J A Belling</i>	<i>9-5-96</i>

3. Regulated Liquid Scintillation Vials are defined as containing H-3 and/or C-14 with a maximum concentration of 0.05 $\mu\text{Ci/mL}$ and vials containing reasonable concentrations of any of the following isotopes listed on our Byproduct Materials License: I-125, I-131, and S-35.

These vials will also be packaged in steel drums for shipment from the company as described above for Deregulated Vials.

4. Aqueous Liquids and Dispersible Solids will generally be disposed of through the sanitary sewer. Because of the large daily and monthly volume of sewage release into the sanitary sewer system, relatively large quantities of the radioisotopes (in the form of aqueous liquids or dispersible solids) which we use in the company can be released into the sanitary system. However, the RPO must be notified prior to release of more than 10 mCi of any radioisotope in the sanitary system.

5. Animal Carcasses containing less than 0.05 $\mu\text{Ci/g}$ in the whole carcass of either C-14 or H-3 may be disposed of without regard for radioactivity. Carcasses containing higher concentrations of C-14 or H-3 or other isotopes will be packaged in a 30 gallon steel drum inside of a 55 gallon steel drum as follows:

Place 2 inches of absorbent inside the inner drum. Insert one 4 mil plastic liner and drape over the top edge of the inner drum. Add at least 4 inches of absorbent and lime. It is important to have most of the absorbent below the carcass and the lime above it. Add animal carcasses, layering with approved absorbent and lime. Use enough lime to prevent odor and bloating of the drum, but leave sufficient room for absorbent to prevent standing liquid as the carcass decomposes. Fill to within 3 inches from the top. Close the liner and seal with tape or wire. Close inner drum, install

T.P.S., INC. PROCEDURES

PAGE 14 OF 14 PAGES

EFFECTIVE DATE: September 6, 1996

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Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>Groteck</i>	<i>9/5/96</i>	<i>M. J. Brundeli</i>	<i>9/5/96</i>	<i>[Signature]</i>	<i>9-5-96</i>

locking ring, and tighten. Fill space between inner and outer drums with approved absorbent. Close outer drum and install locking ring.

6. Biological Waste is waste containing biological, pathogenic, or infectious material or equipment used to handle such material. This material must be autoclaved prior to packaging to render it non-pathogenic. This material will be packaged in steel drums for shipment from the company as follows:

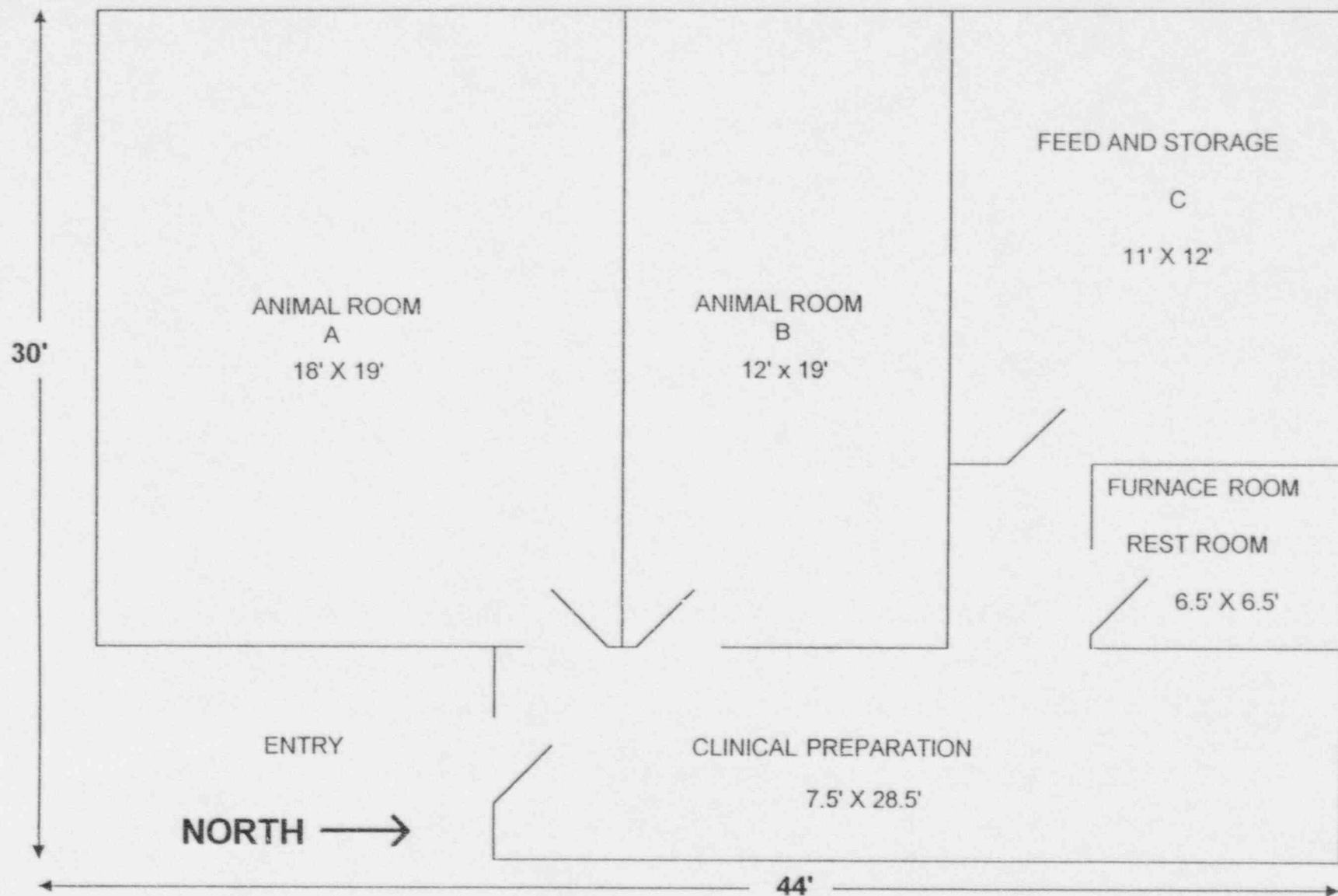
Place 2 inches of absorbent inside inner drum. Insert 4 mil plastic liner and drape over top edge of inner drum. Add biological waste, layering with absorbent and lime (if necessary to reduce odor). Fill to within 3 inches from top. Close liner and seal with tape. Close inner drum, install locking ring, and tighten. Fill space between inner and outer drums with approved absorbent. Close outer drum and install locking ring.

7. For disposal of radioactive material not described above, consult the RPO. Additional information on disposal is provided in "Radioactive Waste Packaging Instructions", Adco Services Inc.

APPENDIX II

Building 101

BUILDING 101



NOV 01 1996

J. A. Botta, Jr., DVM, Ph.D.
Scientific Director
T.P.S., Incorporated
10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

Dear Dr. Botta:

Enclosed is your NRC Material License Number 13-26086-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. You have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. You have notified the U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Licensing Branch, in writing, that activities authorized by the license will be initiated.
3. Notify NRC, in writing, within 30 days:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

- b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
- 4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
- 5. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
- 6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the

J. Botta, Jr.

-3-

General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Loren J. Hueter
Nuclear Materials Licensing Branch

License No.: 13-26086-02

Docket No.: 030-34237

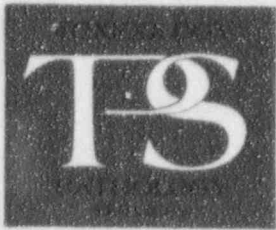
Enclosures: 1. License No. 13-26086-02
2. 10 CFR Part 19
3. 10 CFR Part 20
4. 10 CFR Part 30
5. Form NRC-3
6. NRC Form 313

DOCUMENT NAME: M:\03034237.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	N							
NAME	LHUETER:jaw	YFH							
DATE	10/01/96								

OFFICIAL RECORD COPY



October 24, 1996

Mr. Loren Heuter
Materials Licensing Section
U.S. Nuclear Regulatory commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Heuter:

I am writing to provide additional information and amended information regarding our application for renewal of an NRC license (Control #301810). The amended information is included in the 3 pages enclosed, to be used to replace previous pages in the original application.

Additional information provided in this letter is as follows:

1. All packages are received in the foyer area of Bldg. 104, but radiolabeled materials can be identified by the package label and are immediately taken to Bldg. 101, to be opened at the bench area in Bldg. 101.
2. All radio-labeled materials will be stored in appropriate containers in Bldg. 101.
3. Building 101 has been dedicated to use involving radiolabeled material. This is a small (1400 square feet) concrete block building with only one access door. This building is always locked and access can only be gained by approved personnel. The building is equipped with an electronic security system and any unauthorized attempt to enter the building causes an alarm condition (both local and remote).
4. All waste will be stored in appropriate containers in Bldg. 101 until removed by an approved waste removal contractor, or conveyed to an approved pathological waste incinerator (on site in Bldg. 105), if classified as deregulated material.
5. According to standard operating procedures, lab coats, gloves, boots and masks are routinely used by personnel handling animals. In regard to Bldg. 101 all lab coats used therein will be dedicated to use only in this building until confirmation that they are not contaminated with radiolabeled waste. If contaminated they will be stored with other radioactive waste until removal. If not contaminated they will be sent to the laundry area of Bldg. 102 for cleaning.

RECEIVED

OCT 25 1996

REGION III

Pm: 10-24-96



Letter: Mr. Loren Heuter

October 24, 1996

Page 2

6. As previously indicated, portable caging will not be used. During the time that radiolabeled material will be used, the animals will be in stainless steel metabolism cages in Room A or Room B of Bldg 101. This entire area is secure as described above.

I trust that this additional information clarifies the information submitted in the application and in the Standard Operating Procedures submitted with the application. For the study that is planned, refrigeration is not needed for the test material, and the test material will be stored in a floor safe in the preparation area of Bldg. 101.

If there are additional questions or concerns, do not hesitate to contact me for further clarification or additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "J.A. Botta, Jr.".

James A. Botta, Jr., D.V.M., Ph.D.
Scientific Director, T.P.S., Inc.

Enclosures: Amended data

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

k. Calibration

Survey meter - a battery test of the survey meter will be performed prior to each usage. A complete calibration will be performed every 6 months by the manufacturer:

Ludlum Measurements, Inc.
501 Oak Street
P. O. Box 810
Sweetwater, TX 79556
NRC License No. 4-1963

- l. It is not planned or expected that experiments will be performed with either tritium, iodine-131 or iodine-125 (including synthesis of any iodine compounds) which will exceed levels which, according to NRC guidelines, require that a bioassay program for these radionuclides be established. If such experiments are planned in the future, appropriate bioassay procedures will be submitted to the NRC prior to initiation of the experiments.

m. Animal Experiments

- 1) All experiments will be performed under the supervision of the RPO.
- 2) Animals will be brought into the radioisotope laboratory prior to administration of radioisotopes.
- 3) After administration of a radioisotope to an animal, the animal will be housed in a metabolism cage for the collection of urine and feces until the animal is either sacrificed or testing has demonstrated that the animal is essentially free of radioactivity.
- 4) Waste from animals to which radioisotopes have been administered will be assumed to be radioactive and will be handled as such. Disposal of animal waste will be performed in accordance with directions from the RPO.
- 5) Following termination of an experiment, carcasses from animals that have been sacrificed will be certified by the RPO as being either a) Non-radioactive ($< 0.05 \mu\text{Ci/g}$ of H-3 or C-14) in which case they can be disposed of (incinerated) as non-radioactive waste or b) Radioactive, in which case they will be disposed of by a contract waste disposal company.

T.P.S., INC. PROCEDURES

PAGE 9 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996*

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>R. J. L. L. L.</i>	<i>10/24/96</i>	<i>D. B. L. L.</i>	<i>10/24/96</i>	<i>J. B. L. L.</i>	<i>10/24/96</i>

2. A card file of radioactive materials will be maintained and each time a radioactive material is used, the following information will 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

I. Monitoring

1. Each laboratory in which radioactive materials are handled must be monitored for possible contamination monthly. The following procedure will be used:

A 2" x 2" gauze pad is moistened with ethanol and used to swab a 100 cm² area of work space. The gauze pad is placed in a liquid scintillation vial and the amount of radioactivity present determined by liquid scintillation counting and compared with the natural background of a control gauze pad also moistened with alcohol. Determination of wipe test sample radioactivity will be performed at GFI Pharmaceutical Services, Inc., Evansville, Indiana.

2. The results of the wipe tests, including a sketch of the laboratory identifying the areas monitored, will be submitted to the RPO.
3. If quantities of contamination greater than 200 dpm/100 cm² are found, the entire area should be repeatedly cleaned and monitored until the contamination is removed.

* Note: Page revised and reissued 10/24/96

T.P.S., INC. PROCEDURES

PAGE 13 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996*

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SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>E. W. Leiker</i>	<i>10/24/96</i>	<i>W. J. Miller</i>	<i>10/24/96</i>	<i>[Signature]</i>	<i>10/24/96</i>

Place a second 4 mil plastic liner in the drum. Drape the top portion of the liner over the top edge of the drum. Add scintillation vials to within 3 inches from the top. Do not add absorbent to inner liner with the vials. Close and seal inner liner and outer liner, close drum and install locking ring.

3. Regulated Liquid Scintillation Vials are defined as containing H-3 and/or C-14 with a maximum concentration of $>0.05 \mu\text{Ci/mL}$ and vials containing detectable concentrations of any of the following isotopes listed on our Byproduct Materials License: I-125, I-131, and S-35.

These vials will also be packaged in steel drums for shipment from the company as described above for Deregulated Vials, but labeled as radioactive waste.

4. Aqueous Liquids and Dispersible Solids will generally be disposed of through the sanitary sewer. Because of the large daily and monthly volume of sewage release into the sanitary sewer system, relatively large quantities of the radioisotopes (in the form of aqueous liquids or dispersible solids) which we use in the company can be released into the sanitary system. However, the RPO must be notified prior to release of more than 10 mCi of any radioisotope in the sanitary system.

5. Animal Carcasses containing less than $0.05 \mu\text{Ci/g}$ in the whole carcass of either C-14 or H-3 may be disposed of without regard for radioactivity. Carcasses containing higher concentrations of C-14 or H-3 or other isotopes will be packaged in a 30 gallon steel drum inside of a 55 gallon steel drum as follows:

Place 2 inches of absorbent inside the inner drum. Insert one 4 mil plastic liner and drape over the top edge of the inner drum. Add at least 4 inches of absorbent and lime. It is important to have most of the

* Note: Page revised and reissued 10/24/96

CONVERSATION RECORD

TIME

DATE

10-23-96

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

J. A. Batten, Jr., D.V.M., Ph.D.

T.P.S., Inc

812-

985-5900

SUBJECT

CN 301810

SUMMARY

1. Describe material receipt area, stock storage area & waste storage area & how secured.
2. Confirm lab costs will be used when handling R.M.
3. Confirm animal cages locked when RM studies in progress.
4. FAX or send replacement pages for
 - a. item m-5, on page 7 of application to clarify that animal carcasses containing ≥ 0.05 pc/g can be considered non radioactive, applicable for C-14 and H3
 - b. Item I, 3, on page 9 of 14 of procedures - need to delete the word "appreciably"
 - c. Item C of page 13 of 14 of procedures, need to replace the word "reasonable" with "detectable"
5. Will FAX response tomorrow, 10-24 and overnight hard copy.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Loren Hester

10-23-96

ACTION TAKEN

SIGNATURE

TITLE

DATE



October 11, 1996

Mr. Loren Hueter
Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Hueter:

Based on your comments, please find updated and additional information regarding our application for a new NRC Byproduct Material License. We are resubmitting the application as numerous changes have been made. Any correspondence concerning this application should be directed to me.

Sincerely,

A handwritten signature in dark ink, appearing to read 'J. A. Botta, Jr.', is written over a light-colored background.

J. A. Botta, Jr., D.V.M., Ph.D.
Scientific Director
T.P.S., Inc.

JAB:bjs

Enclosures

RECEIVED
OCT 15 1996
REGION III

301810
OCT 15 1996

□
T.P.S., INC.
10424 MIDDLE MT. VERNON RD.
MT. VERNON, IN 47620

**THE NATIONAL CITY BANK OF
EVANSVILLE**
EVANSVILLE, IN 47705
71-2-863

24613

PAY	DATE	CHECK NO.	CHECK AMOUNT
ONE THOUSAND FIVE HUNDRED DOLLARS AND NO CENTS***	09/04/96	24613	\$1,500.00***

TO
THE
ORDER
OF
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

⑈024613⑈ ⑆086300025⑆ 069604940⑈

T.P.S., INC.

VENDOR NO.

VENDOR NAME

24613

TRANSACTION DATE	REFERENCE	GROSS AMOUNT	DEDUCTION	NET AMOUNT
09/04/96	Application for Material License			\$1,500.00***

CHECK DATE	CHECK NO.	TOTAL GROSS	TOTAL DEDUCTION	CHECK AMOUNT
09/04/96	24613			\$1,500.00***

(7-96)

10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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 JURISDICTIONS.

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



A. NEW LICENSE

13-36086-02



B. AMENDMENT TO LICENSE NUMBER



C. RENEWAL OF LICENSE NUMBER

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

T.P.S., INC.
10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

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

10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John A. LaBudde

TELEPHONE NUMBER

(812) 985-5900

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3M

AMOUNT
ENCLOSED \$ 1,500.00

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, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

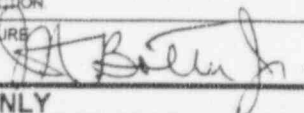
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 82 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

J.A. Botta, Jr., DVM, PhD., Scientific Director



9-5-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
-------------	---------	--------------	-----------------	--------------	----------

\$

APPROVED BY

DATE

APPLICATION FOR MATERIAL LICENSE

5. RADIOACTIVE MATERIAL

Element-Mass Number	Chemical/Physical Form	Maximum Amount
a. Carbon-14	Non-volatile chemical compounds	50 mCi
b. Hydrogen-3	Non-volatile chemical compounds	100 mCi
c. Sulfur-35	Non-volatile chemical compounds	50 mCi
d. Iodine-125	Labeled proteins or biochemicals*	5 mCi
e. Iodine-131	Labeled proteins or biochemicals*	5 mCi

*Non-volatile.

6. PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

Biology experiments in laboratory animals.

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

John A. LaBudde will be the Radiation Protection Officer.

Training and experience of John A. LaBudde, Ph.D. in the handling and use of radioactive isotopes.

TRAINING

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>
Disposal methods. "Hot lab" work and clean-up procedures. Routine sample count- ing and handling.	University of Wisconsin Madison, Wisconsin Dept. of Oncology	1956-59 - While a Ph.D. graduate student.

APPLICATION FOR MATERIAL LICENSE (cont'd)

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (cont'd)

<u>Isotope</u>	<u>Maximum Amt.</u>	<u>Where Experience Was Gained</u>	<u>Duration</u>	<u>Type of Experience</u>
Carbon-14	100 mCi	Dept. of Oncology University of Wisconsin Madison, WI	1956-58	Metabolism studies.
		Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1959-92	Radio-Chemical Synthesis Metabolism studies.
Hydrogen-3	1 Ci	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1959-87	Radio-Chemical Synthesis Metabolism studies.
Sulfur-35	100 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.
Iodine-125	30 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.
Iodine-131	30 mCi	Dept. of Metabolism Bristol-Myers Co. Evansville, IN	1965-75	Metabolism studies.

The duties of the Radiation Protection Officer will be as follows:

- Ensure that radioactive material will be used by or under the direct supervision of individuals specifically listed on the license.
- Ensure that, where appropriate, all personnel wear monitoring equipment and protective clothing when working with radioactive materials.
- Ensure that radioactive materials are properly secured against unauthorized removal at all times when not in use.
- Perform routine inspections of all laboratories in which radioactive materials are used or stored.

APPLICATION FOR MATERIAL LICENSE (cont'd)

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (cont'd)

- e. Ensure that the terms and conditions of the Byproduct Material License are met and that required records are maintained.
- f. Immediately halt any activity judged to be a threat to health, safety, the environment, or a violation of the conditions of the Byproduct Material License or the regulations.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Each individual will, initially and then annually, be instructed in radiation safety. This will include:

- a. The nature of radiation and the hazards that may be encountered.
- b. The biological effects of radiation.
- c. The principles and techniques of radiation protection.

Individuals will be trained and instructed in the handling and use of the radioactive materials with which they are working, with emphasis on their responsibility to promptly report any condition which violates regulations or causes unnecessary exposure to radiation or radioactive material. In addition, instruction shall include appropriate responses to warnings made in the event of an unusual event that may result in exposure to radiation or radioactive material, and include methods to obtain radiation exposure reports.

Experiments will be performed in accord with standard operating procedures for safe handling of radioactive materials as described in Appendix I.

9. FACILITIES AND EQUIPMENT

Radioisotope experiments will be performed in Bldg. 101, Rooms A and B and Clinical Preparation area as shown in Appendix II.

This building is equipped with water and electric outlets. Bench areas are formica and sinks are stainless steel.

Radioisotopes will be stored in locked cabinets or refrigerators. Strong beta emitters will be kept in plexiglass containers. Appropriate shielding such as lead bricks and handling equipment such as remote pipetting device will be available where their use is indicated.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM

A radiation protection program will be maintained in conformance with the regulations in Title 10, Part 20 of the Code of Federal Regulations. This program will include the following:

- a. Prior to the use of radioisotopes at T.P.S., Inc., employees working with the radioisotopes, as well as personnel who may work in the area in which radioisotopes will be present, will be properly instructed with respect to safety problems associated with exposure to the radioactive materials and precautions to be taken. Written laboratory safety standards entitled "Safety Rules and Guidelines for Handling, Storage and Disposal of Radioisotopes" (Appendix I) will be distributed to employees involved in radioisotope work. Special instructions will be provided to animal caretakers as outlined in Section F of the "Safety Rules and Guidelines".
- b. Copies of the regulations governing protection against radiation and copies of the Byproduct Material License will be immediately available.
- c. Form NRC-3 will be posted in all areas where work is conducted with radioactive materials.
- d. Caution signs will be appropriately placed in radiation areas and where radioactive materials are stored.
- e. Containers containing radioactive materials will be appropriately labeled.
- f. Film Badges - all persons who may be exposed to radioactive material will be required to wear film badges. Film badges will be supplied and monitored monthly by Landauer, Glenwood, IL 60425.
- g. Survey Program - Laboratory work areas will be monitored on a monthly basis in accord with the instructions provided in Appendix I. Whenever experiments are performed using a strong beta or gamma emitter, a survey meter will be used to monitor the work area during and after the experiment. The following records will be maintained for both area and surface contamination surveys.
 - 1) The date of the survey,
 - 2) The name of the individual conducting the survey,
 - 3) The instrumentation used to evaluate the radiation and/or contamination levels and;
 - 4) Corrective actions taken if decontamination action levels are exceeded.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

- h. Records Management Program - Record keeping and review will be the responsibility of the Radiation Protection Officer. The following records will be retained.
 - 1) Radioisotope survey records including monthly wipe test results and monthly film badge results.
 - 2) Radioactive materials inventories including receipts, current inventory and disposal.
 - 3) Copies of the Safety Rules and Guidelines for Handling Radioisotopes, copies of the NRC license, amendments to the license, and correspondence relating to radioisotope usage.
- i. Management of Radiation Accidents
 - 1) Ingestion: Persons swallowing radioactive solutions will be treated as for poisoning. Blood and urine samples may be taken in order to assess the degree of exposure.
 - 2) Surface Contamination: Contaminated clothing should be disposed of as radioactive waste. Contamination on the skin should be removed immediately.
 - 3) Minor Injuries: Persons cut by glass, injured by hypodermic needles, etc. under circumstances in which radioactive material may have contaminated the wound, should wash the injured part under a stream of water immediately. Following initial first aid action, medical attention will be obtained promptly. Arrangements should be made to take a surface count.
 - 4) All accidents resulting in the exposure of individuals to radioactive materials must be reported to the Radiation Protection Officer.
- j. The following radiation detection instrument will be used:
 - Survey meter - Ludlum Model 3 Survey Meter with Model 44-21 Beta/Gamma Sandwich Detector. Efficiency: 16% for C-14, 38% for I-125.
 - * Scintillation Counter: Packard Tricarb 1600TR.
 - * Oxidizer: Packard 307
 - * Located at GFI, a nearby laboratory. Anticipated need does not justify purchase of these instruments at this time.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

k. Calibration

Survey meter - a battery test of the survey meter will be performed prior to each usage. A complete calibration will be performed every 6 months by the manufacturer:

Ludlum Measurements, Inc.
501 Oak Street
P. O. Box 810
Sweetwater, TX 79556
NRC License No. 4-1963

1. It is not planned or expected that experiments will be performed with either tritium, iodine-131 or iodine-125 (including synthesis of any iodine compounds) which will exceed levels which, according to NRC guidelines, require that a bioassay program for these radionuclides be established. If such experiments are planned in the future, appropriate bioassay procedures will be submitted to the NRC prior to initiation of the experiments.

m. Animal Experiments

- 1) All experiments will be performed under the supervision of the RPO.
- 2) Animals will be brought into the radioisotope laboratory prior to administration of radioisotopes.
- 3) After administration of a radioisotope to an animal, the animal will be housed in a metabolism cage for the collection of urine and feces until the animal is either sacrificed or testing has demonstrated that the animal is essentially free of radioactivity.
- 4) Waste from animals to which radioisotopes have been administered will be assumed to be radioactive and will be handled as such. Disposal of animal waste will be performed in accordance with directions from the RPO.
- 5) Following termination of an experiment, carcasses from animals that have been sacrificed will be certified by the RPO as being either a) Non-radioactive ($< 0.05 \mu\text{Ci/G}$) in which case they can be disposed of (incinerated) as non-radioactive waste or b) Radioactive, in which case they will be disposed of by a contract waste disposal company.

APPLICATION FOR MATERIAL LICENSE (cont'd)

10. RADIATION SAFETY PROGRAM (cont'd)

m. Animal Experiments (cont'd)

- 6) Prior to removal of cages used in radioisotope experiments from the radioisotope laboratory, solid material will be removed and disposed of as radioactive waste, and the cages will be rinsed with water to remove soluble radioactivity. The cages can then be submitted to the usual animal cage washing procedures. Portable cages will not be used.

11. WASTE DISPOSAL

All materials will be disposed of in accordance with regulations set forth in Sections 20.2001 (a), 20.2002, 20.2003, 20.2004 and 20.2005 of the Code of Federal Regulations. Specifically, most of the soluble and water-dispersible wastes will be disposed of through a sanitary sewer system under conditions authorized and will not exceed the limits described for such disposal.

All solid and liquid waste matter not released into the sewer system will be disposed of by a licensed, commercial, radioactive waste disposal company. We will be utilizing the services of Adco Services, Inc., Tinley Park, Illinois. Waste will be packaged in conformance with "Radioactive Waste Packaging Instructions" provided by Adco Services, Inc.

APPENDIX I

Safety Rules and Guidelines for Handling,
Storage and Disposal of Radioisotopes

T.P.S., INC. PROCEDURES

PAGE 1 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J. A. W. Brown</i>	10/11/96	<i>M. J. K. K. K. K. K.</i>	10/11/96	<i>J. A. W. Brown</i>	10-11-96

TITLE: Safety Rules and Guidelines for Handling, Storage, and Disposal of Radioisotopes

PURPOSE: To provide safety rules and guidelines for handling, storage and disposal of radioisotopes.

SCOPE: Applies to the training of new employees or those with no prior radiation experience by personnel of T.P.S., Inc. for the evaluation of animal studies.

RESPONSIBILITY:

1. The Radiation Protection Officer (RPO) shall maintain that this procedure is used and followed for handling, storage, and disposal of radioisotopes.
2. The Quality Assurance Unit shall review this procedure.
3. It shall be the responsibility of the Scientific Director to evaluate and update this procedure, as required.

PROCEDURES:

- A. Training of New Employees or Those With No Prior Radiation Experience

It is the responsibility of the RPO to ensure that all employees working with radioisotopes be given instruction and training pertaining to the safety problems associated with exposure to sources of ionizing radiation and the precautions and procedures to be taken to minimize such exposure. The employee must demonstrate understanding of the nature of the radiation hazards to be encountered, the biological effects (somatic and genetic) of radiation and the principles and techniques of radiation protection.

T.P.S., INC. PROCEDURES

PAGE 2 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J. G. W. Brown</i>	<i>10/11/96</i>	<i>M. J. S. S. S. S. S.</i>	<i>10/11/96</i>	<i>J. A. S. S. S.</i>	<i>10-11-96</i>

B. Individual User Responsibilities

Each employee working with radioisotopes will:

1. Receive a copy of these guidelines, read it and signify in writing their intent to comply with its provisions.
2. Provide the RPO with a complete employment history involving work with sources of ionizing radiation.
3. Promptly notify the RPO of any accidental inhalation, ingestion, or injury involving radioactive material and carry out the recommended corrective actions.
4. Promptly notify the RPO of any accidental release of radioactive material and carry out the recommended corrective actions.
5. Female employees are encouraged to notify the RPO of any childbearing intention or pregnancy so that risk to the fetus from exposure or potential exposure to sources of ionizing radiation in the laboratory may be minimized.

C. General

1. Radioactive material is to be used only under the direct supervision of a "licensed user", i.e., the Radiation Protection Officer.
2. It is the responsibility of the "licensed user" to see that the rules and regulations governing the safe handling of radioisotopes are known and observed.
3. Each area where radioisotopes are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and words "Caution - Radiation Area". A sign bearing the radiation caution symbol and words "Caution - Radioactive Materials" will also be posted in areas where radioactive materials are stored.

T.P.S., INC. PROCEDURES

PAGE 3 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J.G. W. [Signature]</i>	10/11/96	<i>M. [Signature]</i>	10/11/96	<i>J.A. [Signature]</i>	10-11-96

All individuals working in or frequenting an area where radioactive materials are stored or handled shall be instructed in the safety problems associated with exposure to such materials.

4. All containers used for radioisotopes must be marked with a magenta on yellow radioactive material label identifying the radioactive contents.
5. Form NRC-3, "Notice to Employees", shall be conspicuously posted in a sufficient number of places in the laboratories so that employees may observe a copy on the way to or from the laboratories.
6. A copy of the regulations, license, and operating procedures regarding the use of radioisotopes will be available for employees' examination upon request.
7. All licensed material must be kept under lock and key to prevent unauthorized removal from its place of storage.
8. The rules contained herein are intended as general guidelines and may not cover all situations or radioisotopes. Any questions concerning their application or the handling of radioactive material should be referred to the Radiation Protection Officer.
9. Each licensed user shall post in his or her laboratory a copy of the instructions for packaging radioactive waste.

D. Receipt of Radioactive Materials

1. The RPO will review information on incoming radioactive material and ensure that our license limitations are not exceeded.
2. Radioactive materials received from outside sources are delivered directly to the RPO.

T.P.S., INC. PROCEDURES

PAGE 4 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J. C. Brown</i>	<i>10/11/96</i>	<i>M. J. Scoville</i>	<i>10/11/96</i>	<i>J. A. Bittner Jr</i>	<i>10-11-96</i>

3. Within 3 hours of receipt, the package containing the radioactive material will be 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 the innermost container with a 1" diameter filter paper. Count the paper in a liquid scintillation counter. Dispose of all packaging materials as solid radioactive waste.

4. The following information on all radioactive materials received are to be recorded in a "Radioisotope Log Book" by the RPO.

Material (Name of Compound):
Radioisotope:
Date Received:
Source of Material:
Weight of Material:
Specific Activity:
Total Microcuries:
Results from Wipe Test:
Storage Location:

E. Handling of Radioactive Materials

Most of the radioisotopes used are weak B-emitters (H-3, C-14) and therefore need no additional shielding than their glass container. The major radiation hazard of these radioisotopes results from their accidental ingestion. Therefore, the following rules and procedures will be followed by all personnel handling radioactivity.

T.P.S., INC.
PROCEDURES

PAGE 5 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J. A. Wilson</i>	<i>10/11/96</i>	<i>M. J. Sandell</i>	<i>10/11/96</i>	<i>J. A. Wilson</i>	<i>10-11-96</i>

1. Do not smoke, eat, drink or apply make-up in any radiologically controlled area.
2. Wear appropriate personnel dosimetry devices and protective clothing (lab coat, mask, gloves, booties) when in a radiologically controlled area.
3. Whenever possible, wear protective gloves when handling radioactive materials. Refrain from touching exposed surfaces of skin, especially of the face, while wearing protective gloves. One should also avoid touching door knobs, drawer and cabinet handles and the telephone while wearing protective gloves.
4. Pipette radioactive solutions only by means of mechanical pipetters. Never pipette radioactive solutions by mouth.
5. Use syringes and pipettes to transfer radioactive solutions.
6. Work with plastic-backed absorbent matting beneath the radioactive materials.
7. Work in a shallow tray lined with plastic-backed absorbent matting when working with more than 10 mL of radioactive material in solution.
8. Keep the laboratory neat and clean. Radioactive material work areas should be free of equipment and materials not required for the immediate procedure. Pertinent SOPs should be readily available.
9. Keep clean equipment close at hand or on one side of the work area. As items get used or become contaminated, place them on the other side of the work area or in a disposal container.

T.P.S., INC. PROCEDURES

PAGE 6 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J. Q. Brown</i>	<i>10/11/96</i>	<i>M. J. Scuderi</i>	<i>10/11/96</i>	<i>J. A. Batten Jr</i>	<i>10-11-96</i>

10. Change protective garments before going from contaminated items to clean items.
11. Have an appropriate survey meter handy and turned ON before beginning the procedure. This will enable you to check hands and equipment during and at the end of the procedure. Always check the response of the survey meter before commencing work.
12. Use appropriate shielding. This is an area where consultation with the RPO would be advisable.
13. Label all items to be saved which are radioactive. The label shall contain the radioactive material symbol and the name of the isotope.
14. Wash hands and forearms thoroughly at the conclusion of the radioisotope procedure after first checking them with the survey meter for evidence of contamination.

Note: If contamination of the hand or forearm is found then, without touching anything, notify the RPO at once. After washing hands and forearms survey the work area, floor, your shoes, face, clothing and the clean equipment to be saved from the procedure. Replace any plastic-backed absorbent matting used in the procedure. The absorbent matting must be maintained in a clean condition.

15. Notify the RPO of any loss, spillage, damage or unusual occurrence involving radioactive material.
16. Transport radioactive materials between laboratories or from the laboratory to the waste disposal area in closed, protected containers.
17. Wear eye protection when working with millicurie quantities of unsealed sources of very energetic beta emitters.

T.P.S., INC.
PROCEDURES

PAGE 7 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

SUPERSEDES: September 6, 1996

Prepared By:	Date:	Reviewed By:	Date:	Approved By:	Date:
<i>J.A. Brown</i>	<i>10/11/96</i>	<i>T.J. Scuderi</i>	<i>10/11/96</i>	<i>J.A. Brown</i>	<i>10-11-96</i>

18. Perform work with radioactive materials only in approved laboratories for which you are authorized.

F. Experiments in which Radioisotopes are Used in Animals

1. All experiments will be performed under the supervision of the RPO.
2. Animals will be brought into the radioisotope laboratory prior to administration of radioisotopes.
3. After administration of a radioisotope to an animal, the animal will be housed in a metabolism cage for the collection of urine and feces until the animal is either sacrificed or testing has demonstrated that the animal is essentially free of radioactivity.
4. Waste from animals to which radioisotopes have been administered will be assumed to be radioactive and will be handled as such. Disposal of animal waste will be performed in accordance with directions from the RPO.
5. Following termination of an experiment, carcasses from animals that have been sacrificed will be certified by the RPO as being either a) Non-radioactive ($<0.05 \mu\text{Ci/g}$ of H-3 or C-14) in which case they can be disposed of as non-radioactive waste or b) Radioactive, in which case they will be disposed of by a contract waste disposal company.
6. Prior to removal of cages used in radioisotope experiments from the radioisotope laboratory, solid material will be removed and disposed of as radioactive waste, and the cages will be rinsed with water to remove soluble radioactivity. The cages can then be submitted to the usual animal cage washing procedures. Portable caging will not be used.

T.P.S., INC. PROCEDURES

PAGE 8 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

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<i>J. A. W. B. Jr.</i>	<i>10/11/96</i>	<i>W. B. B. Jr.</i>	<i>10/11/96</i>	<i>J. A. W. B. Jr.</i>	<i>10-11-96</i>

G. Radioactive Material Storage

Radioactive materials will be stored according to the following guidelines:

1. All radiation sources shall be secured against unauthorized removal from their places of storage or use. Radioactive material shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents. Radioactive material in storage shall be provided with reasonable protection against loss, leakage or dispersion by fire effects or by water, hose streams or other means used to fight fire.
2. Strong beta emitters will be kept in plexiglass containers.
3. Shielding for H-3, C-14 and S-35 other than their storage container is not necessary.
4. The amount of shielding placed around stored radioactive materials shall be sufficient to reduce the dose rate at all outer surfaces to less than 5 mrem/hr.

H. Radioactive Materials Inventory

1. An inventory of all radioactive materials will be performed every three months. The following information will appear on the inventory:

Material (Name of Compound)
Radioisotope
Previous Inventory
Amount Received
Amount and Method of Disposal
Current Inventory

T.P.S., INC. PROCEDURES

PAGE 9 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

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<i>J. E. Brown</i>	<i>10/11/96</i>	<i>M. B. Boudin</i>	<i>10/11/96</i>	<i>J. A. Boudin</i>	<i>10-11-96</i>

2. A card file of radioactive materials will be maintained and each time a radioactive material is used, the following information will 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

I. Monitoring

1. Each laboratory in which radioactive materials are handled must be monitored for possible contamination monthly. The following procedure will be used:

A 2" x 2" gauze pad is moistened with ethanol and used to swab a 100 cm² area of work space. The gauze pad is placed in a liquid scintillation vial and the amount of radioactivity present determined by liquid scintillation counting and compared with the natural background of a control gauze pad also moistened with alcohol. Determination of wipe test sample radioactivity will be performed at GFI Pharmaceutical Services, Inc., Evansville, Indiana.

2. The results of the wipe tests, including a sketch of the laboratory identifying the areas monitored, will be submitted to the RPO.
3. If quantities of contamination appreciably greater than 200 dpm/100 cm² are found, the entire area should be repeatedly cleaned and monitored until the contamination is removed.

T.P.S., INC. PROCEDURES

PAGE 10 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

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<i>J.A. W...</i>	<i>10/11/96</i>	<i>M. B...</i>	<i>10/11/96</i>	<i>J. B...</i>	<i>10-11-96</i>

4. Tritium monitoring and protection - Tritium disintegrates to He-3 with the emission of an 18 keV electron. The external hazard from tritium in the elemental form (HT or T₂) is small because of the low energy of the beta particles emitted. The internal hazard from tri-tium is reduced by the fact that absorption is less than 0.1% by the lung tissue and negligible through the skin.

The oxides of tritium (HTO and T₂O), however, are readily absorbed into the body and become uniformly distributed throughout the body fluids within 90 minutes. Almost 100% of tritium water vapor entering the lungs is absorbed and the oxides are absorbed directly through the intact skin as well. Since varying amounts of tritium oxide are associated with the release of any form of tritium, precautions should be taken for controlling exposure to tritium oxide when working with tritium in any form.

Tritium must be handled and stored only in well-ventilated areas under carefully controlled conditions. The use of metal systems is recommended for tritium work to reduce the probability of breakage and because tritium readily diffuses through stopcock grease. It is strongly recommended that all tritium work be done in a hood or glove box equipped with an exhaust system.

All equipment which has come in contact with tritiated water vapor will retain some of the tritium and should be considered contaminated. Persons working with tritiated material during a prolonged procedure must change their gloves hourly in order to avoid having the oxide diffuse through the gloves to the skin.

Air monitoring and urinalysis may be necessary for employees handling millicuric quantities of tritium.

H-3 can be monitored via liquid scintillation counting.

T.P.S., INC. PROCEDURES

PAGE 11 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

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<i>J. G. W. Sunde</i>	<i>10/11/96</i>	<i>M. J. Sunde</i>	<i>10/11/96</i>	<i>J. A. Butler</i>	<i>10-11-96</i>

5. Carbon-14 Monitoring and Protection

Carbon-14 decays to N-14 with emission of an 156 KeV electron.

The primary health hazard from C-14 results from its accidental ingestion. Therefore proper laboratory technique is essential.

C-14 can be monitored via liquid scintillation counting or a survey meter equipped with a thin end window G-M tube.

J. Management of Radiation Accidents

1. Ingestion: Persons swallowing radioactive solutions will be treated as for poisoning. Blood and urine samples may be taken in order to assess the degree of exposure.
2. Surface Contamination: Contaminated clothing shall be disposed of as radioactive waste. Contamination on the skin must be removed immediately.

When the hand is contaminated with a small spot of high specific activity, it is better not to wash the entire hand as this unnecessarily spreads the contamination. Such spots are removed by washing the affected part with cotton applicators. A dry cotton applicator should be used initially followed by washing with applicators moistened in water and/or detergent. Washing with organic solvents should be avoided.

3. Minor Injuries: Persons cut by glass, injured by hypodermic needles, etc., under circumstances in which radioactive material may have contaminated the wound, should wash the injured part under a stream of water immediately. A restrictive bandage may have to be applied if the material is extremely toxic.

T.P.S., INC. PROCEDURES

PAGE 12 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

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<i>J. A. W. Brown</i>	<i>10/11/96</i>	<i>M. J. Zandbergen</i>	<i>10/11/96</i>	<i>J. A. W. Brown</i>	<i>10-11-96</i>

Following this initial first aid action, medical attention must be sought promptly. Arrangements will be made immediately to take a surface count.

4. All accidents resulting in the exposure of individuals to radioactive materials must be reported to the RPO.

K. Radioactive Waste Storage and Disposal

Radioactive waste of the following types may be generated:

1. Uncompacted Dry Solid Waste is defined as containing less than 0.5% by volume of free standing liquids. The chemical form of this waste must be paper, plastic, or glass in nature, or be in a chemical form which can be processed through volume reduction techniques.

Waste containing biological, pathogenic, or infectious material (syringes, test tubes, animal bedding and excreta, etc.) will be packaged as biological material (see Section 6 below). This material will be packaged in steel drums for shipment from the company as follows:

Place one 4 mil plastic liner inside empty drum. Drape top portion of bag over top edge of drum to prevent contaminating the outside. It is recommended that one inch of approved absorbent be placed in the bottom of the drum to absorb any residual liquids present. When drum is full, seal the liner with tape and tuck into drum. Close lid and install locking ring. Label appropriately.

2. Deregulated Scintillation Vials contain only H-3 and/or C-14 with a maximum concentration of 0.05 $\mu\text{Ci/mL}$, or less. These vials will be packaged in steel drums for shipment from the company as follows:

Place a 4 mil plastic liner in the drum. Place 4-6 inches of absorbent in the bottom of the lined drum.

T.P.S., INC. PROCEDURES

PAGE 13 OF 14 PAGES

EFFECTIVE DATE: October 15, 1996

REFERENCE NO. 420.900

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J. A. Bunker	10/11/96	M. J. Bunker	10/11/96	J. A. Bunker	10-11-96

Place a second 4 mil plastic liner in the drum. Drape the top portion of the liner over the top edge of the drum. Add scintillation vials to within 3 inches from the top. Do not add absorbent to inner liner with the vials. Close and seal inner liner and outer liner, close drum and install locking ring.

3. Regulated Liquid Scintillation Vials are defined as containing H-3 and/or C-14 with a maximum concentration of $>0.05 \mu\text{Ci/mL}$ and vials containing reasonable concentrations of any of the following isotopes listed on our Byproduct Materials License: I-125, I-131, and S-35.

These vials will also be packaged in steel drums for shipment from the company as described above for Deregulated Vials, but labeled as radioactive waste.

4. Aqueous Liquids and Dispersible Solids will generally be disposed of through the sanitary sewer. Because of the large daily and monthly volume of sewage release into the sanitary sewer system, relatively large quantities of the radioisotopes (in the form of aqueous liquids or dispersible solids) which we use in the company can be released into the sanitary system. However, the RPO must be notified prior to release of more than 10 mCi of any radioisotope in the sanitary system.

5. Animal Carcasses containing less than $0.05 \mu\text{Ci/g}$ in the whole carcass of either C-14 or H-3 may be disposed of without regard for radioactivity. Carcasses containing higher concentrations of C-14 or H-3 or other isotopes will be packaged in a 30 gallon steel drum inside of a 55 gallon steel drum as follows:

Place 2 inches of absorbent inside the inner drum. Insert one 4 mil plastic liner and drape over the top edge of the inner drum. Add at least 4 inches of absorbent and lime. It is important to have most of the

T.P.S., INC. PROCEDURES

PAGE 14 OF 14 PAGES

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<i>J. Q. Warren</i>	<i>10/11/96</i>	<i>M. J. Frazier</i>	<i>10/11/96</i>	<i>J. A. Batey</i>	<i>10-11-96</i>

absorbent below the carcass and the lime above it. Add animal carcasses, layering with approved absorbent and lime. Use enough lime to prevent odor and bloating of the drum, but leave sufficient room for absorbent to prevent standing liquid as the carcass decomposes. Fill to within 3 inches from the top. Close the liner and seal with tape or wire. Close inner drum, install locking ring, and tighten. Fill space between inner and outer drums with approved absorbent. Close outer drum and install locking ring.

6. Biological Waste is radioactive waste containing biological, pathogenic, or infectious material or equipment used to handle such material. This material must be autoclaved prior to packaging to render it non-pathogenic. This material will be packaged in steel drums for shipment from the company as follows:

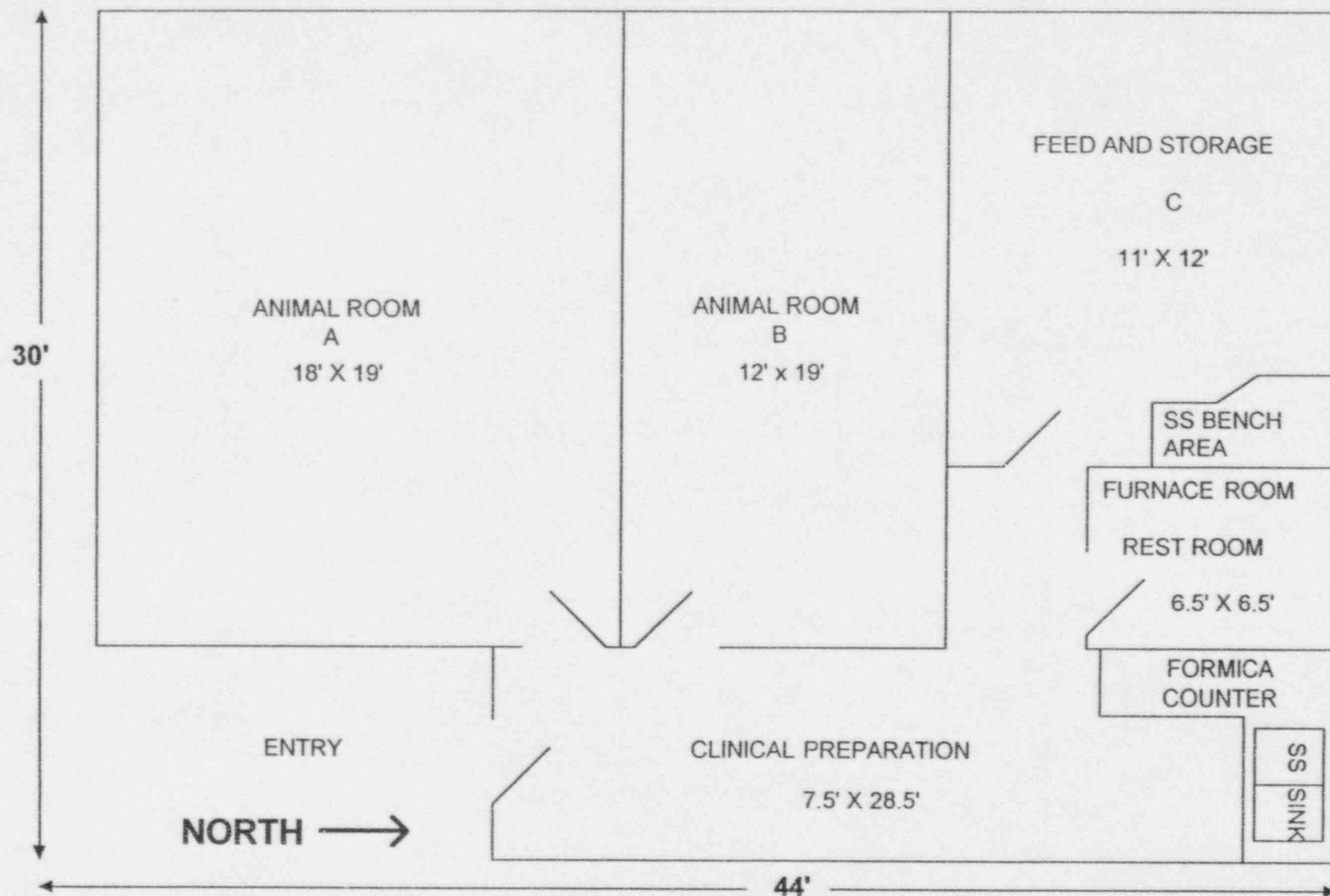
Place 2 inches of absorbent inside inner drum. Insert 4 mil plastic liner and drape over top edge of inner drum. Add biological waste, layering with absorbent and lime (if necessary to reduce odor). Fill to within 3 inches from top. Close liner and seal with tape. Close inner drum, install locking ring, and tighten. Fill space between inner and outer drums with approved absorbent. Close outer drum and install locking ring. Label as radioactive biological waste.

7. For disposal of radioactive material not described above, consult the RPO. Additional information on disposal is provided in "Radioactive Waste Packaging Instructions", Adco Services Inc.

APPENDIX II

Building 101

BUILDING 101



CONVERSATION RECORD

TIME

DATE

10-3-96

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

J. A. Bath, Jr. D.V.M. Ph.D. T.P.S., Inc

812-
985-5900

SUBJECT

CN 301810

SUMMARY

1. Confirm that labeled proteins or biochemical compounds of iodine will not be volatile, and that no synthesizing of radioactive compounds will be done.
2. Confirm that John LaBuddle, RPD, is only person to be listed on license as a user at this time. Also, describe any radioactive experience he has had since 1987.
3. In app. II, please show location of your receipt area, locations of S.S. sinks, bench areas, locked cabinets or refrigerators in which material is stored. Also describe location of any stored waste and how secured.
4. Confirm that procedures for receiving and opening packages will conform to revised 10 CFR Part 20.
5. Confirm lab coats will be used.
6. In SOP you stated in part that animal carcasses will be certified by RPD as being either non-radioactive ($< 0.05 \mu\text{Ci/gm}$) in which case they can be disposed of as non-radioactive waste... please note that this exclusion applies only to H-3 & C-14 (10 CFR 20.2005 (a) (2)) in animal tissue. Please clarify/modify your procedure accordingly.
7. Describe procedures for assuring that animal ingests and vomits are secure when animal studies are in progress.

(over)

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Loren Hunter

10-3-96

ACTION TAKEN

SIGNATURE

TITLE

DATE

8. In SOP (Item I.3 on page 9 of App. I) you stated decontamination action level is "appreciably greater than 200 dpm/cm²". It should not be greater than 200 dpm/100 cm². Please modify.
9. Section 17 should be revised to reflect revised section of new 10 CFR Part 20.
10. Respond in 15 days and reference CN 301810.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 10, 1996

John A. LaBudde
Radiation Safety Officer
T. P. S. Incorporated
10424 Middle Mt. Vernon Road
Mt. Vernon, IN 47620

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter & Application Dated 09/05/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☒ New License ☐ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is nonroutine and has been assigned to Loren Hueter for an expedited review. If you should have any questions please contact Mr. Hueter at (630) 829-9887.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301810
License No. 13-26086-02