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.

OFFICIAL RECORD COPY

Licensee	
1. Antigen Express, Inc.	3. License Number 20-30320-01
2. One Innovation Drive Worcester, Massachusetts 01605-4306	4. Expiration Date September 30, 2001
	5. Docket or Reference No. 030-34182

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. Hydrogen 3	A. Any	A. 200 millicuries
B. Carbon 14	B. Any	B. 50 millicuries
C. Phosphorus 32	C. Any	C. 100 millicuries
D. Phosphorus 33	D. Any	D. 50 millicuries
E. Sulfur 35	E. Any	E. 100 millicuries
F. Chromium 51	F. Any	F. 100 millicuries
G. Iodine 125	G. Any	G. 20 millicuries

9. Authorized use

A. through G. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at One Innovation Drive, Worcester, Massachusetts.

B. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.

In accordance with the requirements set forth in 10 CFR 30.36(b), 40.42(b), and 70.38(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-30320-01

Docket or Reference Number: 030-34182

11. A. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Robert Humphreys	H-3; C-14; P-32; P-33; S-35; Cr-51; and I-125
Minzhen Xu	H-3; C-14; P-32; P-33; S-35; and I-125
Sharlene Adams	H-3; C-14; P-32; P-33; and S-35
Robert Jackson	H-3; C-14; P-32; P-33; and S-35
Christine Barbon	H-3; C-14; P-32; P-33; and S-35

B. The Radiation Safety Officer for this license is Sharlene Adams, Ph.D.

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-30320-01

Docket or Reference Number: 030-34182

17. 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 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 June 18, 1996
B. Letter dated July 22, 1996
C. Letter dated August 15, 1996
D. Letter dated August 21, 1996

For the U.S. Nuclear Regulatory Commission

Date SEP - 6 1996

By ORIGINAL SIGNED BY:
PENNY A. LANZISERA
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

SEP - 6 1996

License No. 20-30320-01
Docket No. 030-34182
Control No. 123358

Robert Humphreys, President
Antigen Express, Inc.
One Innovation Drive
Worcester, MA 01605-4306

Dear Dr. Humphreys:

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 I Office, Licensing Assistance Team, (610) 337-5093 or 5239, 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. Until your license is 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 I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   a. when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name change; or

b. when the mailing address on the license 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. permit anyone to work as an authorized user under the license;

   b. change Radiation Safety Officer;

   c. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   d. add or change the areas of use, or address or addresses of use identified in the license application or on the license; or

   e. 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 a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the 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 "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

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.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

Penny Lanzisera
Division of Nuclear Materials Safety

License No. 20-30320-01
Docket No. 030-34182
Control No. 123358

Enclosures:
1. License No. 20-30320-01
2. 10 CFR Parts 2, 19, 20, 30, and 170
3. NRC Forms 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L2030320.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Lanzisera PL							
DATE	09/03/96		09/ /96		09/ /96		09/ /96	

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P-6

Docket No. 030-34182
Control No. 123358

Penny Lanzisera
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

August 21, 1996

Dear MS. Lanzisera,

The following information is furnished in response to our telephone conversation of August 15, 1996.

1. A copy of the report generated by the EPA's Comply Code, Version 1.2 model for a theoretical release of 1 Ci of 125-I from one of our stacks is enclosed. This release is about 500 times our anticipated release levels and the calculated dose to the highest exposed individual is 1.3 mrem per year.

2. Revised directions for release into the sanitary sewer system are enclosed.

Thank you for your prompt and thorough review. If you require further information please contact me at (617) 589-1867.

Sincerely,

Peter Chin

Peter Chin

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LIQUID RADIOACTIVE WASTE SINK DISPOSAL INSTRUCTIONS

1. Sink disposal is allowed only for liquid waste which is readily dispersable and of biological origin or readily soluble. The RSO must specifically approve of material which is not of biological origin.

2. Only the designated radioactive waste disposal sink may be used for liquid radioactive waste disposal.

3. At the time of disposal the concentrations <u>at the trap</u> must be at or below those concentrations tabulated below.

4. Start the water running at a rate just short of the splash point. This will be 5 to 10 liters per minute and if necessary dilution factors may be calculated for the 5 liters per minute rate. The important point is to wet the sink and pipes so as to minimize sticking problems.

5. Slowly pour the waste directly into the drain.

6. Let the water run for another 5 to 10 minutes to clean the sink and pipes.

7. Record each disposal on the Radioactive Waste Sink Disposal form.

8. If concentration limits allow, annual totals may reach but not exceed those listed below.

SINK DISPOSAL CONCENTRATION LIMITS

Radioisotope	Upper limit (microcuries/liter)
3- Hydrogen	10
14- Carbon	0.3
32- Phosphorus	0.09
33- Phosphorus	0.8
35- Sulfer	1
51- Chromium	5
125- Iodine	0.02

NOTE: In spite of concentration limits, not more than 5 Ci of 3-H, 1 Ci of 14-C, and 1 Ci of all other licensed material may be disposed of in this manner.

08/21/96

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH

THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS

FROM THE COMPLY CODE, VERSION 1.2, SEPT. 1989

Prepared by: Compliance Services, Inc.

Prepared for: Antigen Express
1 Innovation Dr.
Worcester, MA 01605

Prepared for:
U.S. Environmental Protection Agency
Office of Radiation Programs
Washington, D.C. 20460

SCREENING LEVEL 4

DATA ENTERED:

Release Rate

Nuclide		(curies/YEAR)
I-125	D	1.000E+00

Release height 21 meters.

Building height 17 meters.

The source and receptor are not on the same building.

Building width 27 meters.

Building length 67 meters.

STACK DISTANCES, FILE: A:\COMPLY\BIO2STK.DAT

DIR FROM	Distance (meters)
N	556.000
NNE	595.000
NE	635.000
ENE	397.000
E	476.000
ESE	198.000
SE	198.000
SSE	1032.000
S	1587.000
SSW	1032.000
SW	318.000
WSW	238.000
W	635.000
WNW	1111.000
NW	793.000
NNW	556.000

08/21/96

WINDROSE DATA, FILE: A:\COMPLY\WORCROSE.DAT

Source of wind rose data: Summary of Meteroiogical Observations, Surface
Dates of coverage: 1951-1971
Wind rose location: Worcester, MA
Distance to facility: 9200 meters

Percent calm: 0.01

Wind FROM	Frequency	Speed (knots)
N	0.047	8.10
NNE	0.042	8.10
NE	0.063	8.90
ENE	0.047	8.70
E	0.030	7.10
ESE	0.015	5.70
SE	0.015	5.70
SSE	0.015	6.20
S	0.041	7.40
SSW	0.051	8.90
SW	0.096	9.30
WSW	0.115	9.70
W	0.155	10.50
WNW	0.122	12.50
NW	0.089	12.10
NNW	0.046	10.70

He produces his own VEGETABLES at home.
Distance from the SOURCE to the FARM producing MILK is 5000 meters.
Distance from the SOURCE to the FARM producing MEAT is 5000 meters.
NOTES:

The receptor exposed to the highest concentration is located
238. meters to the ENE.
He produces his own VEGETABLES at his home.
He gets his MEAT from a farm located
5000. meters to the E.
He gets his MILK from a farm located
5000. meters to the E.

RESULTS:

WHOLE BODY dose: 1.3 (mrem/year).

WHOLE BODY dose: 1.3 (mrem/year) due to Iodine.

*** COMPLY at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

TELEPHONE CONVERSATON RECORD	**Date:** 8-14-96	**Time:** 3 pm
Mail Control No.: 123358	**License No.:** N/A	**Docket No.:** 030-34182
Person Called: Peter Chin, Consultant	**Organization:** Antigen Express, Inc.	**Telephone Number:**617 589-1867
Person Calling: Penny Lanzisera		
Subject: deficiencies		
Summary: 1) Provide mechanism for complying with 20.1302 for memebers of the public for inhalation. 2) Correct errors on sink disposal guidance: 0.3 uCi/l for C-14, 0.09 uCi/l for P-32, and 0.02 uCi/l for I-125.		
Action Required/Taken: reply		
Signature: Penny Lanzisera	**Date:** 8-14-96	

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ML 10

Antigen Express, Inc.
One Innovation Dr.
Worcester, MA 01605-4306

Office 508 798-6683
Lab 508 757-3701
FAX 508 831-3521
email antigenexp@aol.com

M516
P-6

Docket No. 030-34182
Control No. 123358

Penny Lanzisera
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

August 15, 1996

Dear MS. Lanzisera,

The following information is furnished in response to your letter of July 30, 1996.

1. Our Radiation Safety Officer received training in handling gamma emitters at the University of Lowell, Tufts University, and the University of Massachusetts Medical Center. While she has no direct experience using gamma emitters she has extensive experience controlling external exposure from 32-P. During the initial phase of use of gamma emitters she will be assisted by Dr. Humphreys who has decades of experience working with mCi quantities of this material.

2. We will follow the criteria in Table 1 of Regulatory Guide 8.32 in determining the need for bioassays for tritium.

   When calibrating our 125-I detector we will employ either acrylic or soap as tissue equivalent material. This is routine practice for many licensees. If our preliminary findings indicate that an intake of 10% of an ALI has occurred we will refer the exposed individual to an accredited hospital so that the thyroid burden may be quantitated by their Nuclear Medicine Department. We believe that this method is conservative enough to negate the need for a NIST traceable phantom.

3. The calculation is attached. In this case the DAC is derived from the NALI which, for 125-I, is a factor of 3.3 more restrictive than the SALI and is based upon a 50 rem committed dose equivalent to the thyroid. This calculation is conservative by about a factor of 20 since it assumes an

123358
AUG 12 1996

infinite cloud so that all energy released within the cloud is absorbed within the cloud. If one assumes a cloud with a radius of 2 meters and allows for the escaped fraction, the deep dose equivalent drops to a few tens of microrem per 2000 DAC hours. The deep dose equivalent resulting from submersion in a cloud of radioactive material contributes a significant portion of an individual's total effective dose equivalent only when the airborne nuclides have a very short half-life. In any case, the personnel dosimeters will monitor deep dose from airborne material.

Hoods will run continuously. As shown in the attached calculation we can use up to 175 mCi of 125-I per year without exceeding an average concentration of 3×10^{-13} uCi per cc at the discharge point. Years of experience at other institutions shows that the charcoal bed retains 90% of released 125-I until the dose rate at one foot from the bed as measured with a thin end-window GM reaches 1 mrem per hour. This reading will be taken following each iodination.

4. We will maintain records of all releases into the sanitary sewer system. Instructions to researchers are enclosed.

5. We will not house animals, radioactive or otherwise. Animals will be received in the laboratory, be administered radioactive material, and be sacrificed all on the same day. We have no animal quarters.

6. Our action level for removable contamination on incoming packages of material is 2,200 DPM/100cm^2.

Thank you for your prompt and detailed review of our application. If you require any further informatior please contact our consultant Health Physicist, Mr. Peter Chin, at (617) 589-1867.

Sincerely,

Robert Humphreys

Robert Humphreys
President

Gamma Dose Resulting From Submersion In An Infinite Cloud Of 125-I For 2000 DAC Hours

125-Iodine Photon Emissions:

MeV	Abundance	Energy released per Decay (MeV)
0.004	0.154	0.001
0.027	1.124	0.030
0.031	0.254	0.008
0.036	0.065	0.002
	Total	0.041 MeV

Density of air @ STP - 0.0012 g/cc

1 uCi - 1.32×10^{8} DPH

Concentration 125-I = 3×10^{-8} uCi/cc

1 mrad = 62400 MeV/g (quality factor for photons = 1)

Energy per g per hour =

$(0.041 \text{ MeV/D}) \times (3 \times 10^{-8} \text{uCi/cc}) \times (1.32 \times 10^{8} \text{D/hour}) / (0.0012 \text{ g/cc})$

= 135.3 MeV/g/hour

Energy/g in 2000 hours =

(135.3 Mev/g/hour) x (2000 hour) = 270,600 MeV/g

(270,600 MeV/g)/(62,400 MeV/g/mrem) = 4.3 mrem

Note: The dose to tissue at 1 cm depth is probably about half the air dose.

Stack Discharge Calculations

Maximum allowed concentration - 3×10^{-10} uCi/cc
Fraction of stock released 0.1
Fraction of released material passing through charcoal - 0.1
Air flow - 100 feet/min through a 1' x 4' opening (400 CFM)

1 cubic foot = 2.8×10^{4} cc

Annual flow = (400 CF/min) x (2.8×10^{4} cc/CF) x (5.3×10^{5} min/year)

= 5.9×10^{12} cc/year

Dischargeable activity = (5.9×10^{12} cc/year) x (3×10^{-10} uCi/cc)

= 1.76 mCi/year

This is 1% of the material used so that the annual allowable usage is 176 mCi of 125-I.

Please note that the public is not allowed at the discharge point and that the highest exposed member of the public will receive less than 1% of the dose allowed in 20.1301 as a result of this operation.

LIQUID RADIOACTIVE WASTE SINK DISPOSAL INSTRUCTIONS

1. Sink disposal is allowed only for liquid waste which is readily dispersable and of biological origin or readily soluble. The RSO must specifically approve of material which is not of biological origin.

2. Only the designated radioactive waste disposal sink may be used for liquid radioactive waste disposal.

3. At the time of disposal the concentrations at the trap must be at or below those concentrations tabulated below.

4. Start the water running at a rate just short of the splash point. This will be 5 to 10 liters per minute and if necessary dilution factors may be calculated for the 5 liters per minute rate. The important point is to wet the sink and pipes so as to minimize sticking problems.

5. Slowly pour the waste directly into the drain.

6. Let the water run for another 5 to 10 minutes to clean the sink and pipes.

7. Record each disposal on the Radioactive Waste Sink Disposal form.

8. If concentration limits allow, annual totals may reach but not exceed those listed below.

SINK DISPOSAL CONCENTRATION LIMITS

Radioisotope	Upper limit (microcuries/liter)
3- Hydrogen	10
14- Carbon	0.4
32- Phosphorus	0.5
33- Phosphorus	0.8
35- Sulfer	1
51- Chromium	5
125- Iodine	0.04

NOTE: In spite of concentration limits, not more than 5 Ci of 3-H, 1 Ci of 14-C, and 1 Ci total of all other licensed material may be disposed of in this manner.

RADIOACTIVE WASTE SINK DISPOSAL RECORD

Date Of Disposal	Radioisotope	Activity Microcuries	Concentration Microcuries/l
MONTHLY TOTALS			

JUL 30 1996

Docket No. 030-34182
Control No. 123358

Robert Humphreys, President
Antigen Express, Inc.
One Innovation Drive
Worcester, MA 01605-4306

Dear Dr. Humphreys:

This is in reference to your letter dated July 22, 1996, in response to our letter dated July 3, 1996. In order to continue our review, we need the following additional information:

1. Provide the Radiation Safety Officer's training and experience with gamma emitters similar to chromium-51 and iodine-125.

2. With regards to your bioassay program, please provide your criteria for performing tritium bioassays. Also, you state in your letter that tissue equivalent material will be used for calibrating your iodine bioassay probe. Please confirm that the tissue equivalent material will be intercompared to a NIST traceable phantom prior to use.

3. Item 6 of your letter in response to a description of procedures for complying with 10 CFR 20.1302, states that the deep dose equivalent from a 2,000 hour exposure to a 1 DAC infinite cloud of iodine-125 is less than 5 millirem. By definition, one ALI (which results in a deep dose equivalent of 5 rem) is the exposure at one DAC for 2,000 hours. Please explain your calculations and describe your procedures for complying with 20.1302. Also, Item 7 of your letter indicates that effluent sampling is not required for iodine based upon the assumptions that only 10% is released from the vial and of the 10% released, only 10% passes through the charcoal trap and is released to the environment. Your calculations also assume that the hood is running continuously, instead of only 40 hours a week as is normally the assumption. Please confirm the hood operational time. Also, please provide your maximum iodine-125 use per year which will result in airborne releases of less than 3 x E-10 uCi/ml and provide your mechanism for routinely confirming the efficiency of the charcoal trap.

4. With regards to your sewer release criteria, please provide a copy of the guidance provided to researchers to ensure that the limits in Table 3 to 10 CFR 20 are not exceeded. Also, confirm that records are maintained of all sewer releases.

5. Please provide a description and map of your animal housing facilities.

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6. With regard to your package opening procedures, provide your action levels for package wipes in dpm/100 cm^2.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123358. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:

Penny Lanzisera
Division of Nuclear Materials Safety

Docket No. 030-34182
Control No. 123358

DOCUMENT NAME: R:\WPS\DLTR\L0303418
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Lanzisera							
DATE	07/30/96		07/ /96		07/ /96		07/ /96	

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Antigen Express, Inc.
One Innovation Dr.
Worcester, MA 01605-4306

Office 508 798-6683
Lab 508 757-3701
FAX 508 831-3521
email antigenexp@aol.com

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P-6

Docket No. 030-34182
Control No. 123358

Penny Lanzisera
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

July 22, 1996

Dear MS. Lanzisera,

The following information is furnished in response to your letter of July 3, 1996.

1. Maximum quantities handled per isotope for the referenced individuals are included in Attachment A to this letter. Our Radiation Safety Officer is a full time employee of Antigen Express, Inc.

2. We consider maintenance of the levels of safety described in our Manual to be both a regulatory requirement (20.1101 (a)) and a license condition. The statement on page 1 of our Manual does not allow weakening our safety program.

3. We will store waste in the laboratory space described in our original application. Our knowledge of anticipated usage combined with experience elsewhere indicates that this will be sufficient to meet our needs. Please see item 12 (below) for information on animal housing. Fume hoods are marked on the enclosed drawing (Attachment B). Vendors will be instructed to deliver shipments of licensed material directly to the laboratories.

4. The reference to pocket dosimeters in section 5.1 of our Manual will be deleted.

5. a. Our tritium bioassay procedure is identical to the procedure in Section 12.2 of our Safety Manual. Body burdens will be estimated by assuming that 3-H is distributed in total body water which makes up 60% of body weight.

   b. Iodine bioassays will be performed whenever the activity levels in Table 1 of Regulatory Guide 8.20 are reached.

c. The RSO will further evaluate intakes exceeding 2% of the applicable ALI. Intakes exceeding 10 % of an ALI trip our ALARA Level I threshold and will be treated accordingly.

d. The requested calibration procedure (ATT C) is enclosed. A ratemeter typically allows detection of a thyroid burden of 5 to 10 nCi of 125-I. Assuming a 20% uptake and a 30 day effective half-life a 10 nCi thyroid burden corresponds to a 400 nCi intake occurring three months prior to the measurement. This is 1% of the NALI for 125-I. We may use the scaler if greater sensitivity is desired.

6. With regard to 20.1302, our calculations indicate that the deep dose equivalent from a 2,000 hour exposure to a 1 DAC infinite cloud of 125-I is less than 5 mrem. All other nuclides we will use present less of an exposure risk. Monitoring for this type of exposure will not be necessary.

With regard to 20.1204, our bioassay program was included with the original submission and is further refined in this communication. Based upon anticipated use there will be no requirement to monitor airborne levels in restricted areas.

With regard to public dose, our method for determining public dose (ATT D) from both external and internal exposure is enclosed.

7. Our iodination procedures (ATT E) are enclosed. Based upon projected use we do not anticipate a need for effluent sampling. A four foot wide fume hood with a 100 lfm face velocity with the sash one foot open discharges more than 1 million cubic centimeters of air per minute. This allows an annual discharge of almost 3 mCi of 125-I before the limits in column 1 of Table 2 to Appendix B are reached. A conservative assumption is that 10% of the material used will be released in volatile form. The charcoal trap will catch at least 90% of the released material. The limit in Table B will not be reached unless annual usage exceeds 300 mCi. Our anticipated annual usage of 125-I is about 10% of this.

8. a. Daily wipe tests will be required in areas where soft beta emitters are used when the daily usage exceeds 10 mCi.

b. Weekly surveys will be performed by individuals who are specifically authorized to do so by the RSO. These individuals will have demonstrated competence in performing these activities.

c. Exposure rates exceeding 2 mrem per hour at a distance of 1 foot from the surface of a source of radiation will result in corrective action.

9. We will follow the criteria in IN 94-07 in determining suitability of material for discharge into the sanitary sewer system.

We confirm that records of all disposals into the sanitary sewer will be maintained for commission review.

We anticipate that monthly water usage will exceed 20,000 liters per month. Based on this volume if only single nuclides were discharged the monthly limits would be: 200 mCi of 3-H, 6 mCi of 14-C, 1.8 mCi of 32-P, 16 mCi of 33-P, 20 mCi of 35-S, 100 mCi of 51-Cr, or 0.4 mCi of 125-I. If more than one nuclide is disposed of then the individual nuclide limits are proportionally reduced. For example, if in one month we disposed of 5 mCi of 35-S and 0.5 mCi of 32-P we would have used about 53% of our monthly limit. The sum of the activities disposed of divided by the monthly limit on a per nuclide basis could not total more than 0.47 for further disposals in that month.

10. The president of our company is listed as an authorized user and will have daily involvement with the operational aspects of the radiation protection program. In addition to quarterly ALARA reports, the president will receive quarterly summaries of program activities. At least annually, the performance of the radiation safety staff, program content and implementation will be reviewed by outside auditors who have a combination of training and experience which qualifies them to serve as RSO(s) for a license of this scope. Reports of the findings will be furnished to the RSO and senior management.

Records of the audits, personnel monitoring, training, and effluent monitoring will be maintained for commission review.

11. All of our areas of use will be locked unless occupied. Licensed material will be maintained in line of sig.t or under lock.

12. All animal experiments will be of an acute nature with administration and sacrifice occurring on the same day. All animal care, waste disposal, and cage decontamination will be conducted by authorized users.

13. We agree that contaminated personnel should be removed from a major spill area only if a dire medical need exists.

Contaminated personnel will be decontaminated prior to removal from the scene. Emergency procedures will include the RSO's name and a means of contacting qualified personnel during all working and off hours. The RSO will be notified of all personnel contamination incidents.

14. The lower limit of detection is a function of the background count rate, detection efficiency, and the time constant of the rate meter. Discounting tritium, the most restrictive case is 35-S. Enclosed is a copy (ATT F) of calculations (assuming Poisson distribution) demonstrating that even for 35-S with a fast response setting and a background count rate of 40 CPM, this method will detect activity below the limits in 10 CFR 71.87(i) if 100 square centimeters of package surface is wiped. If 200 square centimeters is wiped one may even assume a normal distribution of counts. We will need to count "labeled package" tritium wipes in a liquid scintillation counter. We note that recent revision to Title 49 has raised the minimum normal form of 3-H requiring labeling to above
100 mCi and it is unlikely that we will ever receive 3-H in that quantity.

15. Long lived waste will be shipped to the Barnwell facility. We will typically employ a broker such as SEG or Radiac Research for each disposal.

The lower limit of detection for 35-S for for the survey meter was discussed in item 14 above.

Please contact our consultant Health Physicist, Mr. Peter Chin at (617) 589-1867 if you require further information.

Sincerely
Robert Humphreys

Robert Humphreys
President

ATTACHMENT A

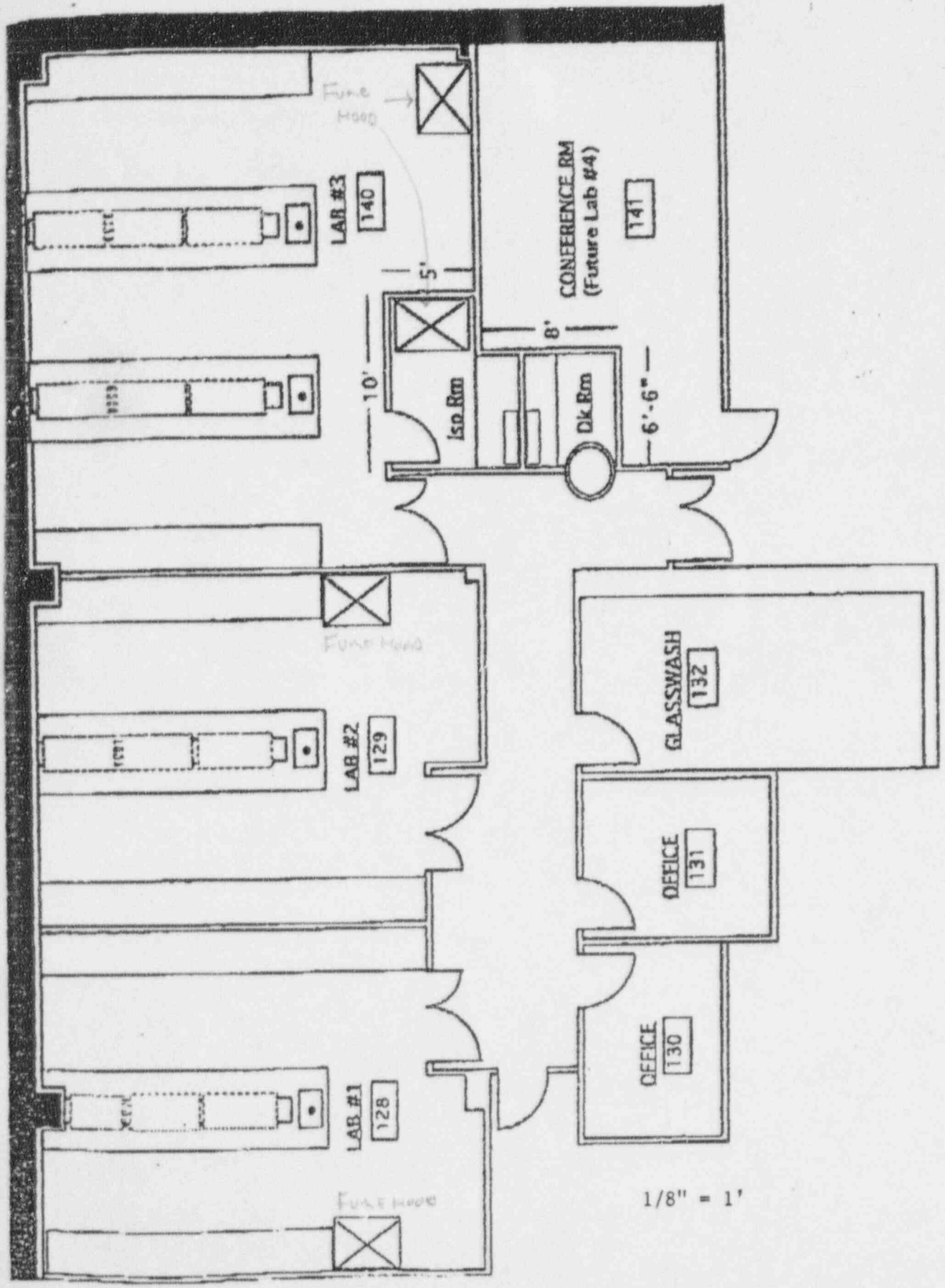
Docket No. 030-34182
Control No. 123358

USER	Activity in use at one time (mCi) 3-H	14-C	32-P	35-S	51-Cr	125-I
Robert Humphreys	5	0.25	5	200	25	10
Minzhen Xu			2	5		1
Sharlene Adams	5		2			
Robert Jackson	0.25		0.5	2		
Christine Barbon	0.1		0.2	2		

In addition Drs. Humphreys and Adams and MS. Barbon have extensive experience using a 3 kCi 137-Cs closed chamber irradiator.

ATT B

Attachment 9.b.
Antigen Express Space at
1 Innovation Drive, Worcester, MA



1/8" = 1'

ATTC

PROCEDURE
CALIBRATION OF LUDLUM 44-3 PROBE
FOR THYROID MONITORING

Material - ^{129}I rod source (NEN Cat. No NES135S or equivalent)
Ludlum ratemeter with 44-3 probe
small screwdriver
3/8" tissue equivalent material (soap, plastic, etc.)
Calibration record sheets
~ 10 uCi 125-I source

1. Perform this procedure only in a low background (500 CPM or lower) area.

2. Typically the lowest scale on these meters has a maximum reading of 500 CPM and is not usable since background readings approach this value.

3. Turn on meter and check batteries. Replace if the battery check shows a reading in the lower quarter of the "BAT TEST" range or lower.

4. Begin calibration on the scale which has a maximum reading of 5,000 CPM.

5. Read and note the background.

6. Place the source next to the sensitive end of the 44-3 probe with the 3/8 inch tissue equivalent material acting as a filter (see drawing below).

7. The meter should give a gross reading which equals the sum of the background and 50 CPM per nanocurie equivalent of 125-I in the source. See note below.

8. If, after the meter has had sufficient time to respond and stabilize, the reading is not as desired, adjust the appropriate potentiometer so that the desired reading is obtained.

9. Make only small adjustments and allow the meter to stabilize between adjustments.

10. Repeat steps 5 through 9 on the next scale.

11. Typically the 129-I source is of insufficient strength to calibrate the highest scale and the ~10 uCi 125-I source is used to calibrate the highest scale by comparison with the second highest scale.

NOTE: Adjust the high voltage only as a last resort.
A convenient value other than 50 CPM per nanocurie may be used but the conversion from CPM to nanocuries must be noted on the meter and in the calibration log.

ATT D

ANTIGEN EXPRESS

METHODS FOR DETERMINING COMPLIANCE
WITH SUBPART D OF 10CFR20

Consistent with the ALARA principle the simplest method of determining compliance should be employed. Existing monitoring information and surveys should be used if feasible.

External Exposure:

It is inconceivable that a member of the public would spend more than 200 hours (1/10 of the annual worker occupancy in any location abutting a restricted area. In addition, distance and shielding provided by the material in the walls will provide an additional ten fold reduction in dose. Thus the highest exposed member of the public can be expected to receive an exposure which does not exceed 1% of the highest occupational exposure received in the restricted area. If the highest occupational external exposure (DDE) does not reach 5 rem in a year the 50 mrem public limit in 20.1302 is met.

Internal Exposure:

The dose to the nearest neighbor may be determined using the EPA Comply program. Public internal exposure at the discharge point may be determined by measuring or calculating airborne effluent concentrations then applying reduction factors for dilution and occupancy. Generally these two factors will each provide at least a thousand fold reduction in exposure.

Docket No. 030-34182
Control No. 123358

Antigen Express
Protein Iodination Procedures

1. Because of the spontaneous oxidation of iodide to volatile elemental iodine there is always an accumulation of vapor phase 125-I in the air space above solutions of 125-I as NaI. The focus of radiation protection efforts when performing iodinations is on limiting airborne 125-I.

2. Only individuals who have been authorized in writing by the RSO may perform iodinations. Inexperienced users are to be supervised by an experienced individual or the RSO until the required techniques are mastered.

3. The RSO must be informed in advance of all iodinations so that she may determine whether bioassays or environmental sampling are required.

4. All iodination procedures are to be performed in the charcoal filtered minihood inside the main fume hood.

5. Lab coats and gloves are required.

6. Hands and work areas are to be monitored frequently with a Geiger counter.

7. Unusual occurrences are to be reported to the RSO.

8. Close-out wipe tests and instrument surveys are to be performed with each procedure.

Detector efficiency=		de	3.5						
Need to detect (DPM)=			2215						
Averaging time (seconds)			4						
Counts in averaging time=			147.6667						
Detected counts in averaging time=			5.168333		Background=		1.333333		
Standard deviation=			2.273397		Sample counts=		5.168333		
Detectable BG CPM=			20		S-BG=		3.835		
BG in counting interval=			1.333333		(S-B)min=		4.360787		
Standard deviation=			1.154701		S min=		5.168386		
Confidence=	Alpha	1.645							
Power=	Beta	1.282							
(S-B)min=	4.360787								
S min	5.168386								
					FAST response calculations				
					based on 4 seconds counting interval				
				Normal distribution Statistics			Poisson Distribution Statistics		
	BG (CPM)		Counts	C/int Min.	Dis/int Min.	DPM Min	C/int Min.	Dis/int Min.	DPM Min
	5		0.333333	3.440052	98.28721	1474.308	2	57.14286	857.1429
	10		0.666667	4.159505	118.843	1782.645	3	85.71429	1285.714
	20		1.333333	5.168386	147.6682	2215.023	4	114.2857	1714.286
	30		2	5.938449	169.67	2545.049	5	142.8571	2142.857
	40		2.666667	6.585856	188.1673	2822.51	5	142.8571	2142.857
					SLOW response calculations				
					based on 22 seconds counting interval				
				Normal distribution Statistics			Poisson Distribution Statistics		
	BG (CPM)		Counts	C/int Min.	Dis/int Min	DPM Min	C/int Min.	Dis/int Min.	DPM Min
	5		1.833333	5.760026	164.5722	448.8332	4	114.2857	311.6883
	10		3.666667	7.418223	211.9492	578.0434	6	171.4286	467.5325
	20		7.333333	9.754074	278.6878	760.0577			
	30		11	11.54267	329.7906	899.4289			
	40		14.66667	13.04905	372.83	1016.809			
	150		55	23.56273	673.2209	1836.057			
	BG (urem/hr)=		7.5						
	cpm/urem=		50						
	Count interval (s)=								

JUL - 3 1996

Docket No. 030-34182
Control No. 123358

Robert Humphreys, President
Antigen Express, Inc.
One Innovation Drive
Worcester, MA 01605-4306

Dear Dr. Humphreys:

This is in reference to your application dated June 18, 1996. In order to continue our review, we need the following additional information:

1. Provide a brief description of the maximum quantities of licensed materials handled per isotope for each individual who will supervise the use of licensed material. Also, please describe the availability of the Radiation Safety Officer (RSO) (e.g., full time or part time).

2. Page 1 of the Radiological Safety Manual (RSM) states that requirements and procedures are subject to change. Confirm that any changes that may degrade safety will require a license amendment prior to implementation.

3. Indicate on a diagram of facilities the location of receipt, waste storage, and animal housing areas. Also, indicate locations of fume hoods.

4. Provide procedures for the calibration of your pocket dosimeters, including:

   a. The training of the individual who will do the calibrating of the pocket dosimeters.

   b. The radioactive source that will be used.

   c. Where the calibration will take place.

   d. Calculations to determine time of exposure.

   e. Step-by-step procedures to perform the calibration.

   f. Frequency of calibration.

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ML 10

5. With regards to you bioassay program, please describe:

   a. your bioassay program for tritium, including the type of bioassay. Regulatory Guide 8.32 is enclosed for guidance.

   b. the frequency for performing iodine bioassays.

   c. the type of action taken when positive results are obtained.

   d. the calibration procedure for instrumentation used for thyroid bioassays, including a description of the phantom used. Also, please indicate why the rate meter is used with the NaI probe instead of the scalar.

6. Describe your procedures for complying with Sections 20.1203, 20.1204, and 20.1302 of 10 CFR Part 20, for procedures such as protein iodinations and tritium labeling experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, and the individuals who will perform the surveys (e.g., radiation safety officer or investigator), equipment to be used, and the procedures for evaluating the results.

7. In support of your request for more than one millicurie of radioiodine, submit special safety instructions to be provided to individuals. Your procedures should include:

   a. A mandatory radiation survey and wipe test for radioactive contamination after each use.

   b. The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine.

   c. A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures.

   d. Procedures for measuring the concentration of radioiodine from the hoods where material is stored and where iodinations are performed.

8. With regards to your survey program, please describe:

   a. the daily survey requirements for areas using low energy beta emitters (e.g., wipes).

   b. who performs the weekly surveys and wipes of laboratories.

   c. the actions limits for area surveys in mR/hr.

9. 10 CFR 20.2003(a)(1) requires that a licensee may discharge licensed material into sanitary sewerage if the material is readily soluble (or is readily dispersible biological material). Information Notice 94-07 (enclosed) provides methods for determining compliance with this requirement which are acceptable to the NRC.

   Please review this Information Notice and provide specific information as to how you will assure that your releases to the sanitary sewerage system will meet the solubility criteria in 10 CFR 20.2003(a)(1). If you wish, you may indicate that you will use one of the methods described in Information Notice 94-07. Otherwise, describe your alternative methodology including the models, calculations, analytical techniques, and quality control measurements as well as the records that will be maintained.

   In addition, provide calculations to show compliance with 10 CFR 20.2003(a)(2)(3)(4) and confirm that records will be maintained of all disposals made into the sanitary sewage system.

10. 10 CFR 20.1101(c) requires that the licensee review the radiation protection program content and implementation at least annually. Submit a description of your program for performing the required annual review. It should include the following criteria:

    a. Senior management oversight of the radiation protection program. Specify the mechanisms that will be used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

    b. Review of the Radiation Safety Officer and staff performance. Specify the minimum qualifications for an individual who will perform this review, and confirm that the results will be reported to senior management.

    c. Audits by the Radiation Safety Officer and staff to determine user compliance with the requirements of the NRC license and your radiation protection program. Audits should include such topics as: reviews of users' inventory and survey records, evaluation of users' radiation safety procedures through observation and discussion, and performance of independent work area surveys.

   Also, please confirm that records of personnel monitoring, training, and effluent monitoring are maintained for Commission review.

11. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application, you did not indicate how you will secure licensed material. Describe how you will preclude the unauthorized removal of licensed material from the place of storage and in unrestricted areas.

12. If licensed materials are to be used in animals, please submit:

    a. a description of the animal's housing facilities, and

    b. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

13. With regards to your emergency procedures, please confirm that:

    a. the procedures include the RSO's name, office telephone number, and a telephone number to be used during off-hours.

    b. the RSO will be notified of all personnel contamination incidents.

    c. the removal of personnel from a major spill area refers to non-contaminated personnel. Otherwise, provide procedures for limiting the spread of contamination.

14. Your procedures for wiping incoming packages to show compliance with 20.1906 describes a procedure for wiping the package with "a piece of paper" and counting the paper with a thin end-window Geiger counter. Please provide the lower limit of detection for all radioisotopes using this method and indicate the established action limits in dpm/100 cm^2.

15. With regards to your waste management program, please describe:

    a. the licensed disposal facility you will utilize in the event that other waste disposal mechanisms are not available (e.g., solid waste with half-life greater than 120 days).

    b. the final survey procedure, including the lower limit of detection, for sulfur-35 waste held for decay-in-storage.

    Also, the carbon-14 and iodine-125 limits listed on page 15 of your RSM and in the instructions for liquid disposal are in error. The procedures also refer to App. B, Table 1, Column 2, instead of Table 3 for the monthly release limits for liquid waste.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123358. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,
ORIGINAL SIGNED BY:
PENNY A. LANZISERA

Penny Lanzisera
Division of Nuclear Materials Safety

Docket No. 030-34182
Control No. 123358

Enclosures:
1. 10 CFR Parts 19 and 20
2. Regulatory Guide 8.32
3. Information Notice 94-07

DOCUMENT NAME: R:\WPS\DLTR\L0303418
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Lanzisera PL							
DATE	07/02/96		07/ /96		07/ /96		07/ /96	

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03620

Antigen Express, Inc.
One Innovation Dr.
Worcester, MA 01605-4306

Office 508 798-6683
Lab 508 757-3701
FAX 508 831-3521
email antigenexp@aol.com

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Safety Section B
475 Allendale Road
King of Prussia, PA 19406

June 18, 1996

Gentlemen:

By this letter and the enclosed documents Antigen Express, Inc. seeks issuance of a Byproduct Material Licence. We are nearing completion of the initial phase of our development, and we plan to begin operations early in the autumn of 1996. We currently occupy space at One Innovation Drive and plan to begin work shortly. We are anxious to have our license to possess and use byproduct material as soon as possible and request expedited review of this application.

The licensed material requested will be used for basic medical and biomedical research. Typical laboratory procedures will involve not more than a few tens of microcuries of radioactive material. However, to allow for future expansion and the decay of waste to background levels, we are requesting possession limits in the multiple-millicurie range. We have developed a radiation safety program for your review which we believe is suitable for use of these quantities. Because our possession limits will be below the quantities described in 10 CFR 30.32 (i) and 10 CFR 30.35 we have submitted neither an emergency response plan nor a decommissioning funding plan.

Pursuant to 10 CFR 170.31 (3)(M) a check in the amount of $1,500.00 is enclosed. If you request further information or have any questions, please contact our consultant Health Physicist, Mr. Peter Chin at (617) 589-1867.

Sincerely,

Robert E. Humphreys

Robert Humphreys
President

123358

JUN 24 1996

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

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-30-90

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.

LL 30320

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

03-34182
03620

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

XX A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER _____

C. RENEWAL OF LICENSE NUMBER _____

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

Antigen Express, Inc.
One Innovation Drive
Worcester, MA 01605

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

Antigen Express, Inc.
One Innovation Drive
Worcester, MA 01605

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Peter Chin

TELEPHONE NUMBER
(617) 589-1867

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND 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 3 M

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

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Robert E. Humphreys	Robert E. HUMPHREYS	President	6-18-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE
				JUN 24 1996

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123358

5. RADIOACTIVE MATERIAL

A. Element	B. Chemical and/or Physical Form	C. Maximum Amount
Hydrogen-3	Any	200 Millicuries
Carbon-14	Any	50 Millicuries
Phosphorus-32	Any	100 Millicuries
Phosphorus 33	Any	50 Millicuries
Sulfur-35	Any	100 Millicuries
Chromium-51	Any	100 Millicuries
Iodine-125	Any	20 Millicuries

6. Purposes For Which Licensed Material Will Be Used

The licenced material requested per this application will be for research and development as defined in 10 CFR 30.4(Q) including in vivo administration to animals. There will be no administration to humans.

7. Individual(s) Responsible For Radiation Safety Program And Their Training And Experience

Individuals who will be allowed to work with millicurie quantities of radioactive material or supervise others in the use of radioactive material are listed below.

Our Radiation Safety Officer is Sharlene Adams, Ph.D. who received more than forty hours of formal training in each of the following areas: Radiation Physics and Instrumentation, Radiation Protection, Mathematics pertaining to radiation use and measurement, and Radiation Biology. The training was received at the University of Lowell, Tufts University, and The University of Massachusetts Medical Center. Dr. Adams has more than eight years of experience working with 2 to 5 mCi quantities of 3-H and 32-P and almost five years experience using a 3 kCi 60-Co irradiator.

Information on the training and experience of others is tabulated on the attached schedule. Please note that all training and use experience is continuous. There have been no lapses.

Our staff will be assisted in the implementation of the radiation safety program by Health Physics personnel from Compliance Services, Inc.

8. Training For Individuals Working In Or Frequenting Restricted Areas

Our training program is outlined in section V. of our "Manual for The Safe Handling of Radioactive Material at Antigen Express, Inc.". This program is to be completed by all personnel frequenting our restricted areas under conditions which are likely to result in a TEDE of 100 mrem in a year. Documentation of this training will be maintained for Commission inspection.

9. **Facilities And Equipment**

We will occupy space at Innovation Drive in the Massachusetts Biotechnology Park in Worcester Massachusetts. A drawing of our laboratories with full descriptions are appended as Attachments 9 a. and 9 b.

As a minimum our radiation detection instrumentation will include:

1. Packard liquid scintillation counter model 2425 or equivalent.

2. 1 Thin end-window Geiger Counter, Ludlum Model 3 with 44-7 probe or equivalent

3. Ludlum Model 2200 Scaler with 44-3 NaI detector or equivalent.

Survey instruments will be calibrated by the manufacturer or another licensed calibration facility annually or following repair. At this time calibrations will be performed by Ludlum Measurements of Sweetwater, Texas, or Radiation Consultants, Inc., 2318 Center Street, Deer Park, Texas, 77537. If other services are used we will maintain a copy of all appropriate certifications for Commission inspection.

10. **Radiation Protection Program**

Our radiation safety program is outlined in the enclosed "Manual for The Safe Handling of Radioactive Material at Antigen Express, Inc.".

11. **Waste Management**

We will dispose of radioactive waste by decay to background and discharge into the sanitary sewer system. Based upon the half-lives involved and our anticipated levels of use, we have requested possession limits which will eliminate the need to ship waste to a licensed disposal facility. Our waste management program is outlined in section VI of the enclosed "Manual for The Safe Handling of Radioactive Material at Antigen Express, Inc.".

TRAINING AND EXPERIENCE

Robert E. Humphreys, M.D., Ph.D.

	Location	Clock Hours	On The Job Hrs
Radiation Physics & Instrumentation	Yale & US Navy	80	100
Rad. Protection	US Navy	40	400+
Mathematics	Yale	200	200
Radiation Biology	Yale	100	200
Radiopharmaceutical Chemistry	Yale	50	200

Dr. Humphreys has years of hands on experience using up to 200 mCi of loose 3-H, 14-C, 32-P, 35-S, 51-Cr, 125-I, and 131-I.

Minzhen Xu, M.D., Ph.D.

	Location	Clock Hours	On The Job Hrs
Radiation Physics & Instrumentation	Jiangxi Medical College & Shanghai 2nd Med. Col.	80	80
Rad. Protection	Jiangxi Medical College & Shanghai 2nd Med. Col.	40	100
Mathematics	Jiangxi Medical College & Shanghai 2nd Med. Col.	80	200
Radiation Biology	Shanghai 2nd Med. Col.	60	60
Radiopharmaceutical Chemistry	Shanghai 2nd Med. Col.	40	40

Dr. Xu has more than 500 hours of hands on experience using 1 to 5 mCi quantities of loose 32-P, 35-S, and 125-I at Shanghai 2nd Medical College and the University of Massachusetts Medical Center.

TRAINING AND EXPERIENCE

Robert G. Jackson, M.S.

	Location	Clock Hours	On The Job Hrs
Radiation Physics & Instrumentation	MBRI, Worcester, MA		10
Rad. Protection	U. Mass. Lowell MBRI	20	200
Mathematics	U. Mass. Lowell MBRI	200+	10
Radiation Biology	U. Mass. Lowell	20	

Mr. Jackson has more than 200 hours of hands on experience using 0.25 to 2 mCi of 3-H, 35-S, and 32-P in laboratory experiments.

Christine Marie Barbon, B.S.

	Location	Clock Hours	On The Job Hrs
Radiation Physics & Instrumentation	MBRI, Worcester, MA		10
Rad. Protection	U. Mass. Lowell MBRI	20	200
Mathematics	U. Mass. Lowell MBRI	200+	10
Radiation Biology	U. Mass. Lowell	20	

Mr. Jackson has more than 200 hours of hands on experience using 0.25 to 2 mCi of 3-H, 35-S, and 32-P in laboratory experiments.

SHARLENE ADAMS, Ph.D.
33 Sheridan Drive, Apt. 11
Shrewsbury, MA 01545
Home (508) 842 3326
Work (508) 757 3701

SUMMARY

Creative, hard-working, well-organized individual with strong capabilities in Immunology, T cell assay development, and project management.

WORK EXPERIENCE

1995-present Antigen Express, Inc., One Innovation Dr., Worcester, MA 01605

Director of Immunology, and a Founding Scientist, 1995-present

- Participated heavily in AE start-up planning, and acted as the liaison between AE and the Massachusetts Biotechnology Research Institute (MBRI) during the establishment of the AE laboratory facility at the Innovation Center, MBRI, Worcester, MA
- Developed and performed a series of T cell functional assays to identify and examine novel compounds which enhance or inhibit antigen presentation
- Identified and characterized the first class of novel drug candidates for AE
- Performed basic *in vivo* immunological testing of the lead drug candidates
- Performed basic toxicological studies on the lead drug candidates
- Recruited, trained and supervised a research associate
- Acted as radiation safety officer for AE, and as the liaison between AE and the Department of Radiation Safety, UMASS Medical School, Worcester
- Acted as the liaison between AE and the Department of Laboratory Animal Medicine, UMASS Medical School, Worcester
- Acted as the internal manager of the portion of AE's start-up funds coming from MBRI, and as the liaison between AE and the purchasing agent for MBRI
- Participated heavily in writing two patents and one SBIR application for AE

EDUCATION AND TRAINING

Postdoctoral Research Associate, Department of Pharmacology, University of Massachusetts Medical School, Worcester, MA, 1992-1995. Instructor, 1994.
Immunology/Virology Fellowship, University of Massachusetts Medical School, 1992-1994.

- Conducted the basic science research which built the platform of data and technology on which Antigen Express, Inc. received its start-up funds in 1995

Publications:

•**S. Adams** and R.E.Humphreys. Invariant chain peptides enhancing or inhibiting presentation of antigenic peptides by major histocompatibility complex class II molecules. *European Journal of Immunology* 25: 1693-1702, (1995).

•M. Xu, M. Daibata, **S. Adams**, R.E. Humphreys and V.E. Reyes. Charging of peptides to MHC class II molecules during proteolysis of Ii. In R.E. Humphreys and S.K. Pierce (eds.), *Antigen Processing and Presentation*, Academic Press, San Diego, CA, pp. 227-241 (1994).

•M. Salomon, **S. Adams**, A. Pardanani, S. Vazquez, R.E. Humphreys and R.A. Lew. Comparison of actual and random-frequency-model distributions of peptide scavenging and T cell-presented sites in antigenic proteins. *Vaccine* 11(10): 1067-1073 (1993).

Ph.D., Immunology, Tufts University, Boston, MA, 1986-1992.

Thesis title: The T Cell Receptor Vβ Gene Repertoire of Autoimmune T Cells in the (SWRxNZB)F1 Murine Model of Lupus Nephritis.

Publications:

•C. Mao, G.E. Osman, **S. Adams** and S.K. Datta. TCR α-chain repertoire of pathogenic autoantibody-inducing T cells in lupus mice. *Journal of Immunology* 152(3): 1462-1470 (1994).

•C. Mohan, **S. Adams**, V. Stanik and S.K. Datta. Nucleosome: a major immunogen for pathogenic autoantibody-inducing T cells of lupus. *Journal of Experimental Medicine* 177: 1367-1381 (1993).

•D.V. Vlahakos, M.H. Foster, **S. Adams**, M. Katz, A.A. Ucci, K.J. Barrett, S.K. Datta and M.P. Madaio. Anti-DNA antibodies form immune deposits at distinct glomerular and vascular sites. *Kidney International* 41: 1690-1700 (1992).

•**S. Adams**, P. Leblanc and S.K. Datta. Junctional region sequences of T cell receptor β chain gene expressed by pathogenic anti-DNA autoantibody-inducing T helper cells from lupus mice: possible selection by cationic autoantigens. *Proceedings of the National Academy of Sciences, USA* 88 (24): 11271-11275 (1991).

•**S. Adams**, T. Zordan, K. Sainis and S.K. Datta. T cell receptor Vβ genes expressed by IgG anti-DNA autoantibody-inducing T cells in lupus nephritis: forbidden receptors and double negative T cells. *European Journal of Immunology* 20: 1435-1443 (1990).

Abstracts:

•C. Mohan, **S. Adams**, V. Stanik and S. K. Datta. Nucleosome: a major immunogen for the pathogenic autoantibody-inducing T cells of lupus. *Journal of Immunology* 150 (8, Part II): 256A (1993).

•**S. Adams**, P. Leblanc and S.K. Datta. Pathogenic Tcell receptors in murine lupus nephritis: possible selection by cationic autoantigens. *Arthritis and Rheumatism* 34(9): S44, (1991, Supplement).

•**S. Adams**, T. Zordan and S.K. Datta. T cell receptor Vβ gene usage by pathogenic anti-DNA autoantibody-inducing T cells. *FASEB Journal* 3: 2604 (1989).

B.Sc., Biology, University of Lowell, Lowell, MA, 1982-1986.

Awards:

Summa Cum Laude, University of Lowell; President's Key for Distinguished Academic Achievement, College of Pure and Applied Sciences; Dean's Award for Outstanding Academic Achievement; Biological Sciences Award; Senior Year Scholarship for Academic Merit.

Christine Marie Barbon
104 Brookline Street
Worcester,MA. 01603 (508) 757-5442

EMPLOYMENT:

9/11/95-Present: Antigen Express Inc, Robert E. Humphreys Ph.D.,President
One Innovation Drive/BiotechIII/ Massachusetts Biotech Research Institute
Worcester,MA.01605

Title:Research Associate-Molecular Immunology

Responsibilities/Techniques:Involved in autoimmune disease research, namely in allele-specific drug screening & design exploring the molecular mechanism and therapeutic, adjuvant activity of Ii-KEY-derived compounds. Specific duties include: Performing T-cell functional assays [redacted] secondary, multi-phase HT-2 indicator assays; including 3H pulsing, harvesting and data calculation. Other duties include: Cell culture of murine T-cell hybridomas & APC lines, PE-avidin staining, irradiator and beta-scope usage. Also function as a radiation safety co-officer performing the appropriate radiation safety checks, record keeping, solid waste & biohazard control. Properly kept a patent document-type lab notebook, took regular lab inventory checks and did product ordering. Computer experience in WordPerfect & QuattroPro.

4/92-9/95, Dept.of Pediatric Immunology, Principal Investigator John L. Sullivan M.D.
University of Massachusetts Medical Ctr./ Biotech II
Worcester, MA. 01605

Title:Professional Research Lab Technician

Responsibilities/Techniques:Pursued studies of HIV/AIDS disease pathogenesis, drug resistance and vaccine research, primarily [illegible]3(BL-3) environment. Specific duties included: Separation of patient blood samples by Ficoll-Hypaque method. S[illegible]ration of healthy donor cells, after electroplatelctphoresis, for stimulation and co-culturing of patient specimens including lymphocytes, plasma, whole blood, lymphoid tissue and cerebral spinal fluid, as well as animal tissues and BLCLines.
Set-up, maintenance & sampling of cultures for qualitative & quantitative assessments of viral load and drug resistance. Cryogenics involving viral isolates, patient samples & other tissues. Specialized staining & slide-making techniques. Aliquoting, logging & storage procedures for materials needing further assays.

1/90-5/92, Dept. of Molecular Genetics & Microbiology, Principal Investigator Allan Jacobson Ph.D.
University of Massachusetts Medical School Worcester, MA. 01605

Title:Research Assistant/Tech.

Responsibilities/Techniques: Involved in research focusing on post-transcriptional regulation in eukaryotes. Duties included making stock solutions, lab inventory, plasmid DNA preps, RNA isolations & degradation assays and making of radioactive probes. Hybridizations, Northern blotting, gel electrophoresis, OD spectrophotometry and the usage of a betascope were also necessary

EDUCATION:

1988-93 B.S. in Biology, Natural Science Minor from Worcester State College, Worcester, MA. 01602
Graduated with special honors from the Chi-Iota chapter of the Tri-Beta Biological Honor Society.Served for two years as an officer in this organization. 1991-92 President; 1990-91 Historian, still an active member.

1984-1988 Graduated from Holy Name Central Catholic High School 144 Granite St. Worc.,MA.01604

VOLUNTEER ACTIVITIES/PERSONAL:

Summer,1990:Preparation of lab materials & growth media for summer classes at Worcester State College. Involved with Arts at the Angels, an arts and humanities presentation organization in Worcester County; sing in the OLA Adult Choir. Volunteered in co-teaching a confirmation preparatory class. Member of Mechanics Hall in Worcester. Enjoy the outdoors,travel,antique restoration,gardening,crafting,cooking and music.Married in 1993.

Robert G. Jackson

21 Makos Street
Tyngsboro, MA 01879
(508) 649-2549

Professional Experience:

Molecular Biologist 09/95 to Present
Antigen Express, Worcester, MA

Responsibilities: Research and development of an ELISA to screen active compounds for experimental rheumatoidal arthritis pharmaceutical drugs. The assay detects binding and spilling of synthesized peptide sequences at a MHC Cl II site. Human (DR) and mouse (I-E) α & β chains were cloned, sequenced, expressed (dimers), purified, and used as the major component in the assay. The purified dimers were bound to the plate using monoclonal antibodies and incubated with antigenic peptide. The bound antigenic peptide was then used to screen peptides of various sequence for the ability to spill and block the MHC Cl II active site. Release of the antigenic peptide and blockage of the MHC Cl II binding site were verified by colorimetric testing.

Experienced in the following techniques: Cloning, sequencing, PCR, protein and antibody purification, DNA and plasmid purification, transfection, transformation, plaque assays, immunoprecipitation assays, electroporation, cell culture, and other standard molecular biology techniques.

Other: Chemical safety officer, CPR and First Aid certified.

Graduate Laboratory Assistant 08/94 to 06/95
University of Massachusetts Lowell, Lowell, MA

Responsibilities: Instructed Life Science Laboratory, which included: set up, lesson and test preparation, lecturing and grading.

Research Assistant 05/94 to 08/94
Biodegradable Polymer Research Center, Lowell, MA

Responsibilities: Optimized biodegradation conditions of polymers. Utilized protein affinity binding and size exclusion chromatography for enzyme purification.

Senior Development Planner 11/87 to 04/92
Hughes Aircraft Company, Los Angeles, CA

Responsibilities: Support manufacturing tasks from the design to delivery of satellite payload power supplies. Evaluated manufacturing resources, developed master schedules for production process flow and detailed assembly instructions.

Education:

University of Massachusetts Lowell,
Lowell, Massachusetts
Masters of Science, October 1995
Major: Biotechnology

Thesis: Biodegradation of Isotactic and Syndiotactic Poly (3-Hydroxybutyrate) using *Penicillium funiculosum.*

Abstract: The biodegradation feasibility of natural and synthetic poly(3-hydroxybutyrate) was studied using the fungus *Penicillium funiculosum*. A Bio-growth chamber was developed to maximize cellular growth and, thus, optimize the production of P3HB-depolymerase. Total, cellular, and extracellular protein concentrations were determined using standard assays; depolymerase activity was monitored using colorimetric and turbidimetric assays. The deploymerases responsible for degradation were isolated and purified for characterization using ammonium sulfate fractionation and hydrophobic, size exclusion chromatography techniques. *P. funiclosum* and the isolated depolymerases were shown to be effective in the biodegradation of synthetic P3HB.

State University of New York, Buffalo, New York
Bachelor of Science, December 1986
Major: Business Administration/Marketing

Canton ATC, Canton, New York
Associate of Science, June 1984
Major: Engineering Science

Presentations and publications: Presented Thesis research at NSF Biodegradable Polymer Research Center technical meetings, October 1994, April 1995 and 1996; American Chemical Society, April 1995; Gordon Conference, March 1995. Published in Polymer Preprints 36 (1) 1995, "Biodegradation of Natural/Syndiotactic Poly (3-Hydroxybutyrate) Blends" and publication in work, "Syndiotactic or Isotactic Poly (3-Hydroxybutyrate) as a Sole Carbon Source for *Penicillium funiculosum*".

Scientific Societies: Sigma Xi.

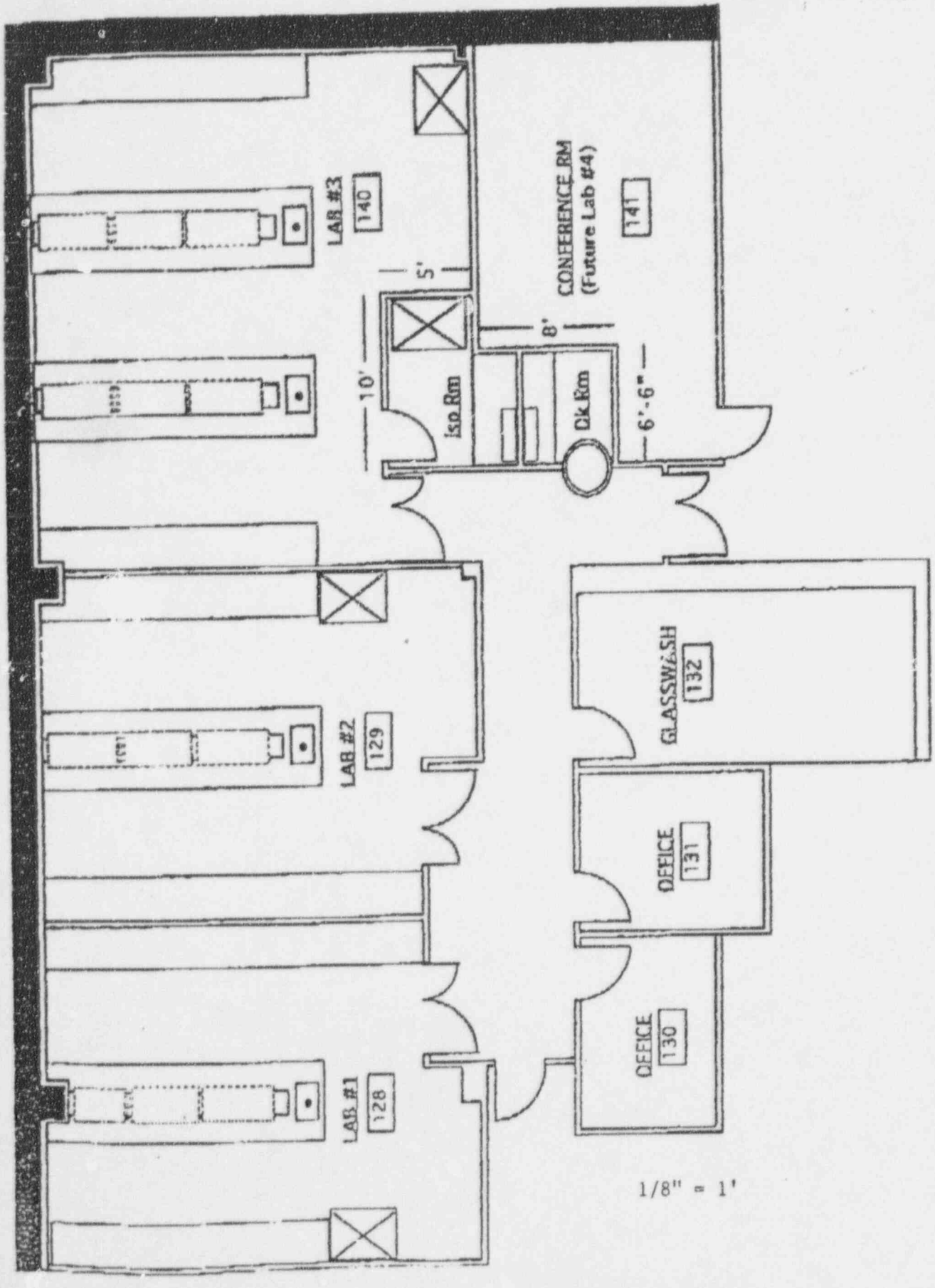
Computer skills: Microsoft Word, Delta Graph, Cricket Graph, Microsoft Excel.

References: References available upon request.

Attachment 9 a. (Space ,at One Innovation Drive)

Our space is shown in the drawing labeled Antigen Express, Inc. Laboratories and Offices. Radioactive material will be used in the areas labeled Lab #1, Lab #2, and Lab #3. All surfaces are of non-porous material. Fume hoods will have a minimum average face velocity of 100 LF/M. Proper face velocity will be confirmed twice annually. Radioactive waste will be stored in the laboratories or dishwashing room

Attachment 9.b.
Antigen Express Space at
1 Innovation Drive, Worcester, MA



1/8" = 1'

123358

ANTIGEN EXPRESS, INC.

ALARA PROGRAM

Issued June 12, 1996

COMMITMENT

Antigen Express is committed to the program described herein for keeping individual and collective occupational and public radiation doses as low as reasonably achievable (ALARA)

IMPLEMENTATION

Once each calendar quarter, the Radiation Safety Officer will examine exposure and effluent records and compare them to the attached Tables of Investigational Levels.

If the records indicate levels below those of Level I, no action is required unless such action is deemed appropriate by the RSO.

If the records indicate levels exceeding Level I but below Level II the RSO shall conduct a documented investigation.

For records indication that Level II thresholds have been exceeded the RSO shall investigate and shall document remedial action.

All above quarterly actions will be reported in writing to management.

Signature of Certifying Official

Robert E. Humphreys

Signature

Robert E. HUMPHREYS

Name (Type or Print)

President.

Title

123358

ANTIGEN EXPRESS, Inc.
ALARA Action Levels

Type of Dose	Quarterly Level I	Quarterly Level II
TEDE	0.125 rem	0.375 rem
Eye dose equivalent	0.375 rem	1.125 rem
Skin (shallow dose)	1.250 rem	3.750 rem
Extremity	1.250 rem	3.750 rem
Deep dose + CEDE to	1.250 rem	3.750 rem

See 10 CFR 20.1003 for definitions

CONCENTRATION LIMITS

Nuclide	Quarterly (uCi/ml) Level I Limit	Quarterly (uCi/ml) Level II Limit
3-H	air $2x10^{-8}$	$6x10^{-8}$
	water $2x10^{-4}$	$6x10^{-4}$
14-C	air $6x10^{-10}$	$2x10^{-9}$
	water $6x10^{-6}$	$2x10^{-5}$
32-P	air $2x10^{-10}$	$6x10^{-10}$
	water $2x10^{-6}$	$6x10^{-6}$
33-P	air $8x10^{-10}$	$2x10^{-9}$
	water $2x10^{-5}$	$7x10^{-5}$
35-S	air $6x10^{-10}$	$2x10^{-9}$
	water $2x10^{-5}$	$6x10^{-5}$
51-Cr	air $6x10^{-9}$	$2x10^{-8}$
	water $8x10^{-5}$	$2x10^{-4}$
125-I	air $6x10^{-11}$	$2x10^{-10}$
	water $4x10^{-7}$	$1x10^{-6}$

Note: Satisfying the annual requirements of the EPA Comply program at any time is taken as proof that air effluent levels are ALARA.

MANUAL FOR THE SAFE HANDLING OF RADIOACTIVE MATERIAL AT ANTIGEN EXPRESS, INC.

ISSUED

MAY, 1996

ANTIGEN EXPRESS, INCORPORATED

RADIOLOGICAL SAFETY MANUAL

TABLE OF CONTENTS

I. INTRODUCTION

The primary purpose of this manual is to provide for the safety and protection of employees of Antigen Express, Incorporated who are involved with the use of radioactive materials. The policies and procedures established within this manual are designed to comply with Federal and State Agency requirements governing the use of radioactive materials.

Responsibility for proper safe handling of licenced materials is shared by both management and individual employees. The policies and procedures established in this manual are designed to maintain exposures to ionizing radiation As Low As Reasonably Achievable (ALARA). The cooperation of all parties is essential to achieving this important goal.

Any individual who encounters difficulties implementing safety steps in a procedure or who becomes aware that a procedure may be improved shall bring the problem or recommendation to the attention of their supervisor or the Radiation Safety Officer.

Any employee violating or disregarding a policy, safety step, or regulation detailed in this manual is subject to disciplinary action.

The requirements and procedures detailed in this manual are subject to change as deemed necessary or desirable by the Radiation Safety Officer. Variance from these requirements or procedures may be granted only by the Radiation Safety Officer via written instructions and only when said variance will not result in any violation of Federal or State Regulatory Agency requirements or radioactive material license conditions.

II. SCOPE

This radiation safety manual covers the proper safety precautions, training requirements, operating and emergency procedures to be used by all Antigen Express employees engaged in radioactive material utilization for the Corporation.

III. APPLICABILITY

The requirements and procedures detailed in this manual apply to all employees of Antigen Express, Incorporated including contract employees and visitors.

IV. DUTIES AND RESPONSIBILITIES

1.0 Radiation Safety Officer

The Radiation Safety Officer (RSO) is responsible for assuring the radiation safety of all employees. The RSO is responsible for the establishment, staffing, and supervision of the radiation safety program. In general, the RSO shall be responsible for assuring that compliance in the following areas is achieved.

1.1 Registration of workers who will be involved in the handling of radioactive materials.

1.2 Provision of radiation safety training to all employees who are required to work with radioactive material.

1.3 Provision, as necessary, of personnel monitoring for radiation exposure.

1.4 Provision, as necessary, of radioisotope laboratory inspections, radiation surveys, and area monitoring.

1.5 Proper collection, packaging, and disposal of radioactive waste.

1.6 Provision of adequate and properly calibrated radiation safety instruments.

1.7 Leak testing of sealed sources.

1.8 Maintaining control of the procurement of radioactive materials

1.9 Monitoring all shipments of radioactive materials (both incoming and outgoing).

1.10 Following-up radiation incidents and special decontamination operations.

1.11 Maintaining required radiation protection records.

1.12 Approving all proposed use of radioactive material.

1.13 Proper storage of bulk quantities of radioactive materials.

1.14 Developing and distributing radiation safety operating, and emergency procedures.

1.15 Acquiring and maintaining State and Federal radioactive material utilization licences and/or registrations.

1.16 Assuring that all restricted areas are properly posted.

2:0 Radiation Workers

All radiation workers are expected to be thoroughly familiar with the rules and regulations set forth in this manual and shall be responsible for:

2.1 Following implicitly all instructions, directions, procedures and other information supplied to him/her by the company in regards to the performance of his/her duties.

2.2 Maintaining personal exposures to ionizing radiation to levels that are as low as possible and practicable.

2.3 Reporting to their supervisor and/or Radiation safety operations personnel any incident or conditions that may affect the safe operation of licenced materials.

3.0 Laboratory Supervisors

The laboratory supervisors are expected to be thoroughly familiar with the rules and regulations set forth in this manual and shall be responsible for:

3.1 Assuring that all applicable rules and regulations are enforced in their work area.

3.2 Notifying the radiation safety staff and/or Radiation Safety Officer of all changes in their work with radioactive materials which may impact operating procedures, personnel exposures or radioactive releases to the environment.

3.3 Seeing that all use of radioactive material is consistent with the goal of maintaining radiation doses as low as reasonably achievable.

3.4 Maintaining a current inventory of radioactive material for which he/she is responsible.

3.5 Assuring that the volume of radioactive waste generated is minimized.

3.6 Assuring that all workers under his/her supervision have satisfactory completed the corporate training requirements prior to initiating work with radioactive materials.

3.7 Assuring that unusual occurrences, spills and/or releases of radioactive material are promptly reported to the radiation safety staff.

3.8 Assuring that all necessary safety equipment and supplies are present and in good working condition.

3.9 Assuring that all required records are kept current.

Supervisors continued

3.10 Assuring that all required wipe tests and surveys are performed in a timely manner.

3.11 Assuring that radioactive materials under his/her control are properly stored

3.12 Obtaining specific permission from the Radiation Safety Officer prior to initialing new work with radioactive materials.

3.13 Approving orders for radioactive material, if so authorized.

V. TRAINING PROGRAM

BASIC RADIATION SAFETY TRAINING COURSE

1.0 Training Program Synopsis

The following is a synopsis of the training course given by the radiation safety staff. Attendance and completion is mandatory for all individuals whose potential occupational exposure is as high as 100 mrem TEDE per year. An annual refresher is also required for those employees who wish to continue to maintain their status as radiation workers. Ancillary personnel who are not assigned to routinely work in restricted areas but who have occasion to enter restricted areas to perform specific duties will be trained in the areas in this outline, but not in as great detail.

OBJECTIVE

To introduce radiation workers to the subject of radiation safety and to familiarize them with some of the radiation hazards which a radiation worker may encounter.

DURATION

2 HOURS (for radiation workers)

HANDOUTS

Radiation Safety Manual Handbook
Registration Form
Requests for exposure history
10 CFR 19 & 20
NRC Form 4
Reg. Guide 8.13

APPLICABILITY

All employees who are required to work with or perform operations in Radiation controlled areas.

TABLE OF CONTENTS

I. Introduction

II. Fundamentals Of Radiation Safety

A. Atomic Structure
B. Characteristics Of Radiation
C. Units Of Radiation
D. Hazards Of Exposure To Radiation
E. Levels Of Radiation From Licenced Materials
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A. Use Of Personnel Monitoring Equipment
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C. High Radiation Area
D. Contaminated Area
E. Airborne Area
F. Storage Area

V. LABORATORY PROCEDURES

A. Radioactive Materials Safety Guidelines
B. Survey Requirements
C. Contamination Control
D. Storage Of Radioactive Materials
E. Accountability Of Radioactive Materials
F. Radioactive Waste Disposal

VI. EMERGENCY PROCEDURES

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B. Personnel Contamination
C. Loss Of Licenced Material
D. Others

VII. LEGAL REQUIREMENTS

A. NRC Requirements
B. Workers Rights And Responsibilities
C. License Conditions

VI. RADIATION SAFETY REQUIREMENTS

1.0 Procedural Compliance

For legal and safety reasons it is necessary that procedures in this manual be followed by all employees. Any individual who encounters difficulties implementing safety steps in a procedure or who becomes aware that a procedure can be improved upon shall bring the problem or recommendation to the attention of their supervisor or the Radiation Safety Officer.

2.0 Posting And Labeling Requirements

The following signs and documents are to be posted in the locations indicated. These posting and labeling requirements are designed to achieve compliance with Part 20 of Title 10 CFR and posted material may not be removed without permission of the RSO.

2.1 Caution Radioactive Material Signs-	Entryways to the laboratory areas and on refrigerators and freezers used for storage of greater than exempt quantities of radioactive material
2.2 Caution Radiation Area Signs-	Areas where a major portion of the body could receive a dose of 5 mrem in one hour.
2.3 Form NRC-3 (map)-	In sufficient locations to assure a reasonable expectation of workers seeing same coming from or going to work
2.4 Notification of the availability of Parts 19 and 20 of Title 10 CFR and the NRC license and all correspondence associated with same	As for item 2.3 above
2.5 Emergency Telephone Numbers-	As for item 2.1 above except for freezers and refrigerators
2.6 Labels indicating the presence of radioactive material including information as to the isotope, quantity, and date	All unattended containers of radioactive material

3.0 Control Of Radiation Restricted Areas

3.1 General Restrictions

Federal regulations define restricted areas as areas access to which is controlled for radiation protection purposes. In general, any area where radioactive material is used or stored is to be treated as a restricted area. While access to such areas is not totally denied to individuals such as sales representatives or clerical staff, special precautions are to be followed. All individuals who are not Antigen Express radiation workers shall be accompanied by a knowledgeable radiation worker while in a restricted area and shall be advised of the presence of the radiation sources and the steps to be followed to minimize radiation exposure.

3.2 Minors and Pregnant Women

Antigen Express requires all radiation workers to be 18 years of age or older. Minors are not allowed to use radiation sources. Pregnant women are required, as are all employees, to take every reasonable precaution to minimize their own radiation dose. This requirement exists for the protection of the fetus as well as the employee. Any employee who believes that she may be pregnant may declare that pregnancy by completing the Antigen Express Declared Pregnant Woman Form. The Radiation Safety Officer and staff will provide pregnant women with information, advice and counseling and will work with them to minimize the radiation dose to the fetus. The maximum permissible dose during gestation is 0.5 rem. It may be necessary to modify the work situation to stay within the limit. A woman may "undeclare" the pregnancy as she sees fit.

3.3 Moonlighting

Occupational dose limits apply to the total dose received under all work situations. Employees of Antigen Express who work elsewhere under conditions which may result in an occupational radiation dose are required to notify our Radiation Safety Officer of the additional exposure.

4.0 General Operating Procedures

General Precautions

1) Protective clothing is to be worn in laboratory areas. Generally lab coats, gloves and closed toe shoes are sufficient, but for special procedures additional protection may be needed. Please consult Radiation Safety.

2) Issued personnel dosimetry (badges) is to be used as directed.

3) Wear gloves. Double gloves are recommended for higher level procedures.

4) Eating, drinking, smoking, mouth pipetting, application of cosmetics and storage of food stuffs are prohibited where unsealed radioactive materials are used or stored.

5) Use appropriate shielding during operations and storage.

6) Plan all operations employing time, distance, and shielding to minimize radiation exposure.

7) Wash and monitor your hands after each use of radioactive material.

8) Adequate ventilation is to be used when the likelihood of airborne radioactive material exists.

9) Bench tops should be protected with removable absorbent material.

10) Use survey meters often to check for contamination and adequacy of shielding.

11) Use remote handling devices to manipulate "hot" (contact dose rate >1 rem/hour) sources.

12) Check to be sure that survey instruments are operable prior to use.

13) Specific precautions for the use of ^{32}P, ^{125}I, and ^{35}S are contained in sections 4.1 through 4.3 of this manual.

14) Work with radioactive animals is allowed only with specific permission from the Radiation Safety Officer. In general:

    a. Radioactive animals are to be housed in labeled cages separate from other animals.

    b. Only acute (survival <24 hours) experiments are allowed.

    c. Cages must be cleaned separately and checked for contamination prior to returning to general use.

    d. The Radiation Safety Officer must specifically authorize each use of radioactive material in animals.

4.1 Precautions for use of ^{32}P

1. ^{32}P has a physical half-life of 14.3 days.

2. While the maximum range of the 1.7 MeV (E max) beta particle in tissue equivalent material is about 8 mm (~3/8"), most of the energy is deposited in the first 2 mm of material. The maximum range in air is about 20 feet.

3. While "whole-body" radiation doses are not of particular concern with this radioisotope, skin doses and particularly eye doses are of concern. Most special precautions for use of this radioisotope are directed at minimizing the risk of eye and skin doses.

4. Bremhstrallung (x-rays) produced by the interaction of the beta with materials having a high atomic number (such as lead) may be as energetic as the beta.

5. "Low Z" material (plastic or occasionally glass) should be used for first shielding of this nuclide.

6. Infinitely thick (3/8" plastic) shielding must be employed when handling 1 mCi or more of this nuclide. Such shielding is strongly recommended when handling smaller quantities. If needed, secondary lead shielding (1/8" to 1/2") should be added.

7. Eye protection is mandatory when handling 10 mCi or more of this nuclide. Eye protection is strongly recommended when handling smaller quantities.

8. Shielding referred to above may be the classic bench top "L" shields or may be localized test-tube rack of individual vial shields. If "L" shields or hood sashes are employed as eye shielding the user must be extremely careful to have the sash in a low enough position to offer proper protection and must be certain not to "look around" L shields. Glasses or goggles are the preferred form of eye shielding.

9. All precautions designed to minimize the risk of accidental intakes of radionuclides are to be followed.

4.2 Precautions for using ^{125}I

1. The physical half-life of ^{125}I is 60 days.

2. ^{125}I decays by electron capture with a complex spectrum of x-rays and gamma rays with an average energy of about 0.03 MeV.

3. For the quantities typically encountered at Antigen Express, 1/16" thick lead will provide excellent shielding. This material is available as lead flashing in the plumbing department of Home Depot for about $1 per pound. Multiple wrappings of this flexible material may be used if needed.

4. Because of the risk of release of elemental $^{125}I_2$ work with more than a few uCi of ^{125}I as NaI must be performed in the charcoal filtered minihood in a standard fume hood. All appropriate effluent and breathing zone monitoring must accompany iodinations.

5. Uses of bound ^{125}I which result in the significant release of a substantial portion of free iodine are prohibited without specific permission of the Radiation Safety Officer.

6. All precautions designed to minimize the risks of intake of radioactive material are to be followed.

4.3 Precautions for the use of ^{35}S

1. ^{35}S has a physical half-life of 88 days.

2. Even in direct contact with the skin only about 1/3 of the 0.167 MeV (E max) energy beta will penetrate to the basal layer of the skin. Air and clothing provide excellent shielding for the quantities of ^{35}S in use at Antigen Express. Typically, no shielding beyond the shipping or reaction vessel need be employed.

3. There have been reports in the literature of volatile products being generated in shipping vials of ^{35}S. These products seem to increase with increasing numbers of freeze thaw cycles.

4. Even though the fractions released are apt to be very small, it is best to open vials containing 1 mCi or more of this nuclide in the fume hood and to minimize the number of freeze thaw cycles.

5. Incubators which are routinely used with ^{35}S loaded culture medium are to be placed on the routine wipe test list.

6. All precautions designed to minimize the risks of intake of radioactive material are to be employed.

5.0 Radiation Exposure Monitoring

All Antigen Express personnel are expected to make every reasonable effort to maintain radiation doses as low as reasonably achievable (ALARA). At present Part 20 of Title 10 Code of Federal Regulations establishes maximum permissible occupational radiation doses as follows:

Type of Dose	Annual Limit (Rem)
TEDE	5*
Eyes dose equivalent	15
Shallow dose equivalent (skin)	50
Any extremity	50
Deep dose equivalent + CEDE to any organ not listed above	50
Individual members of the public	0.100

*- Does not include accident conditions or planned special exposures.

5.1 External exposure Monitoring (Badges)

Each month, all personnel whose work situation indicates the possibility of receiving 10% of a maximum permissible radiation dose will be issued commercially processed personnel dosimetry consisting of film badges for monitoring body exposure and ring badges for monitoring hand exposure. Badges will be obtained from and processed by a NAVLAP certified vendor. These badges are considered an essential part of the Radiation Safety Program and must be worn when working with millicurie amounts of gamma or hard beta emitters. Personnel working in situations with a lower risk of radiation exposure may be issued other types of dosimetry such as direct reading pocket dosimeters or TLD badges and the exchange rate may be less frequent (quarterly).

5.2 Monitoring Internal Exposure (Bioassays)

Individuals using radioactive material in quantities specified in Section 13 of this manual are required to have bioassays. Individuals working with smaller quantities of radioactive material will be required to have bioassays if the nature of the work or the chemical or physical form indicates that volatility, aerosols or dusts may be a significant problem. This service is available to individuals working with smaller quantities of radioactive materials. Please see Section 13.0.

6.0 Procurement, Receipt, and Inventory

Antigen Express has been issued a Byproduct Materials Licence by the U.S. Nuclear Regulatory Commission. This license establishes possession limits for each allowed radionuclide and requires that an inventory be kept to assure that those limits are not exceeded. To assure compliance with that requirement a system for maintaining an inventory and approval of purchases of radioactive material has been established. Laboratory supervisors are responsible for implementation of this system.

6.1 Procurement

All purchase orders for radioactive material must be approved by a laboratory supervisor who has been authorized to do so by the Radiation Safety Officer. Before approving any order for radioactive material the supervisor must determine that receipt of the material will not result in Antigen Express exceeding its possession limits. Following approval, material may be ordered through normal channels.

6.2 Receipt

Vendors shall be directed to arrange for delivery of radioactive material during normal working hours. The laboratory supervisor who initially approved the order is responsible for seeing that the package is checked in accordance with the "Radioisotope Receiving Form".

6.3 Inventory

The radioactive material inventory is to be updated each month in accordance with the attached "Inventory Procedures". Please note that the NRC issued possession limits take into account all radioactive material on the premises whether it is working stock or waste. Diligent and timely keeping of these records is the only way of assuring that our limits are not exceeded.

7.0 Radiation Surveys

A radiation survey consists of an evaluation of the radiation hazards which may exist in an area and, as appropriate, involves the use of instrumentation. Surveys may be as simple as a quick check with a Geiger counter or as complex as a detailed analysis including evaluation of personnel traffic patterns with time and motion studies and elaborate environmental sampling. Basically Antigen Express conducts four types of radiation surveys.

7.1 Worker Surveys

These are the instrument checks of individual work stations mentioned in Item 10, of the General Precautions Section (4.0) and are performed to determine that no detectable contamination has resulted form a single use of radioactive material. While no records need be kept for these surveys, if personnel contamination or high levels of equipment contamination are noted follow-up procedures are needed, and if the thresholds in the Action Level Table in Section 10 of this manual are reached, records must be kept.

7.2 Exit Surveys

These are instrument surveys performed prior to the end of each work day during which radioactive material was used and are designed to confirm that all radioactive material is properly stored behind necessary shielding and that contamination is minimal. A record of these surveys must be kept on the "Exit Survey Form" and if Action Level thresholds are reached corrective actions must be taken and documented. If no radioactive material is used during a given day the entry "No Use" should be made for that day.

7.3 Weekly Surveys

These are performed by designated staff and consist of instrument surveys and wipe tests of potentially contaminated surfaces. Results of these weekly surveys indicate the effectiveness of the other surveys and the overall safety program. Results will be recorded on the "Weekly Survey Form".

7.4 Air Sampling

Whenever a volatile radioactive material is handled in significant quantities or when the nature of a procedure indicates that a release of radioactive material is likely, appropriate air handling protection is to be employed. Typically this means using the fume hood for these procedures. Whenever a release which approaches the concentration limits of Table 1 or 2 of Appendix B of 10 CFR 20 is expected, air sampling, breathing zone and/or effluent, is to be instituted.

8.0 Radioactive Waste

Treatment and disposal of radioactive waste are labor intensive and costly procedures. In accordance with the national effort to minimize the amount of waste shipped to the existing burial grounds for disposal, personnel at Antigen Express are expected to employ all legal and environmentally sound waste volume reduction techniques. Generally these include careful planning of experimental procedures so as to minimize the generation of radioactive waste including purchasing and using the minimum amount of radioactive material needed for experimental purposes, using "minivials" and "deregulated" cocktail for liquid scintillation counting, and being exceedingly careful to keep radioactive and general waste separate. Following the procedures outlined below will allow us to process radioactive waste in manner that will minimize the volume shipped for burial and allow the proper packaging of waste for disposal. Because of the half-lives of licensed material which may be possessed, there should be no need for disposal via a licensed burial site. We are dependent on your cooperation and remind you that all work involving the use of radioactive material is dependent on safe and legal disposal of the waste. This may necessitate the use of 3 or more separate containers for the solid waste and the same number for the liquid waste.

8.1 General Information

Radioactive waste will be processed, packaged and disposed of by radiation safety personnel on an as needed basis. All waste is to be labeled with the radionuclide(s) present and the amount of each radionuclide present. When short lived nuclides ($t_{1/2} < 3$ months) are present, the date the waste was placed in the container must also be entered. If any of the materials in the radioactive waste are reactive or toxic they must also be noted on the label. Chelating agents such as EDTA and citric acid must also be noted.

8.2 Decay To Background Levels

Radioactive waste in any form with a half-life of 100 days or shorter may be held for ten half-lives, surveyed with an appropriate instrument, and if found to be at background levels disposed of as not radioactive. The survey must be performed in a low background area (0.05 mrem/hour), labels indicating the contents are radioactive removed or defaced, and a record of the disposal maintained on the "Decayed Radioactive Waste Disposal Record" form. This procedure is to be carried out by designated radiation safety staff only.

8.3 Liquid Scintillation Vials

These are to be sorted into two major groups based upon the type of cocktail used. Group I consists of vials in which the cocktail is a "deregulated" type or water. Group II consists of vials using a cocktail containing a regulated solvent such as xylene, toluene or dioxane. Within each major category the vials are to be subgrouped by isotope in the following manner.

Subgroups - A. Vials containing only nuclides with a half-life of 65 days or shorter

B. Vials containing nuclides with a half-life longer than 65 days

8.4 Liquid Radioactive Waste

The preferred method for handling liquid radioactive waste with a half-life of 65 days or shorter is decay to background followed by sink disposal. Unwieldy volumes of short-lived waste or waste with a half-life longer than 65 days may be disposed of into the sanitary sewer system if they are dispensable in water and are disposed of into a designated receptacle.
As of this writing the annual limit on sink disposal are for all radioisotopes other than ^{3}H and ^{14}C is 1 Ci (in aggregate). In addition, concentration limits are established in 10 CFR 20 appendix B Table 3. Examples of these limits are listed below and are not to be exceeded.

Concentration limits per appendix B, Table 1, Column 2

Nuclide	Concentration (uCi/liter)
3-H	10
14-C	0.4
32-P	0.09
33-P	0.8
35-S	1
51-Cr	5
125-I	0.04

Liquid radioactive waste is to be collected and stored in plastic jars. Liquids not suitable for storage in plastic may be stored in glass if a secondary containment system is used to guard against a total release in case of breakage. Please leave sufficient space in these containers to allow for thermal expansion of the contents.

All sink disposal shall be carried out and records maintained in accordance with the attached "Radioactive Waste Sink Disposal Instructions." Individuals are to maintain appropriate records of waste placed into holding containers.

8.5 Solid Waste

Dry solid waste is to be placed only in plastic lined containers clearly marked "Radioactive" and a separate container is to be used for each category of radionuclides listed below. "DRY" solid waste may contain no more than 0.5% liquid so that while a few microliters of liquid in each test tube may not be of concern, just a few centrifuge tubes containing 5 to 15 milliliters of liquid are a matter of concern. These should be emptied into the liquid waste prior to disposal of the container as solid. It is the responsibility of the individual disposing of the waste to update the waste disposal form on a regular basis.

Categories - I - long lived (t 1/2 > 65 days) radionuclides such as 35-S.

II - radionuclides for long term decay (15 <t 1/2< 65 days) such as 125-I.

III - radionuclides for short term delay (t 1/2 <15 days) such as 32-P .

8.6 Animal Carcasses

Because this type of waste is particularly difficult to dispose of, care should be taken to minimize generation of radioactive animal carcasses. Animals used in this manner may not be allowed to enter the food chain. Animal carcasses containing only 3-H or 14-C at concentrations below 0.05 uCi per gram are legally not radioactive. Carcasses above this limit or containing other radioisotopes are legally radioactive and must be stored frozen in the designated -20 freezer for decay to background levels or commercial disposal. As of this writing the only options for long-lived material are incineration by SEG or burial at Barnwell. Neither is cheap.

9.0 EMERGENCY PROCEDURES

These procedures are designed to allow Antigen Express personnel to deal with major unintentional releases and accidents in such a way that contamination and injury are minimized. All radiation workers are to review and be familiar with these procedures. Most spills are minor and can be dealt with on an informal basis.

9.1 ACCIDENTS INVOLVING RADIOACTIVE DUSTS, MISTS, FUMES,VAPORS, AND GASES

1. Notify all other persons to vacate the room immediately.
2. If the task can be performed easily and safely, hold breath and close air vents if the quantity released is likely to result in the limits in 10 CFR 20 Appendix B being exceeded.
3. Vacate the room, seal off area, if possible.
4. Notify the Radiation Safety staff at once.
5. Ascertain that all doors giving access to the room are closed. Post conspicuous warnings or guards to prevent accidental opening of the doors.
6. Monitor all persons suspected of contamination. Proceed with decontamination of personnel. See Decontamination Procedures below.
7. Report at once to the Radiation Safety Officer all known or suspected inhalations of radioactive materials.
8. Evaluate the hazard and the safety devices necessary for safe reentry.
9. Determine the cause of contamination and rectify the condition.
10. Decontaminate the area only upon the advice of the Radiation Safety Officer.
11. Perform an air survey of the area before permitting work to be resumed.
12. Submit a complete history of the accident and subsequent activities to the Radiation Safety Officer.
13. The Radiation Safety Officer will determine the need for bioassays.

9.2 MAJOR SPILLS, INVOLVING RADIATION HAZARDS TO PERSONNEL

1. Notify all persons not involved in the spill to vacate the room at once. Limit the movement of displaced persons to confine the spread of contamination.
2. If the spill is liquid and the hands are protected, right the container; otherwise, use a stick or lever.
3. If the spill is on the skin, flush thoroughly.
4. If the spill is on the clothing, discard outer or protective clothing at once.
5. Switch off all fans.
6. Vacate the rooms.
7. Notify the Radiation Safety Officer as soon as possible.
8. Take immediate steps to decontaminate personnel involved as necessary. Please see Decontamination Procedures below.
9. Decontaminate the area (personnel involved in decontamination must be adequately protected). The Radiation Safety Officer will direct the decontamination.
10. Monitor all persons involved in the spill and cleaning.
11. Permit no person to resume work in the area without the approval of the Radiation Safety Officer.
12. A complete history of the accident and subsequent activity must be submitted to the Radiation Safety Officer.

9.3 SPILLS, INVOLVING MINIMAL RADIATION HAZARD TO PERSONNEL

1. Immediately notify all other persons in the room and area.
2. Survey people before they become dispersed, and change clothes as necessary.
3. Permit only those individuals needed to deal with the spill into the area.
4. Confine the spill immediately.
   A. Liquid spills: Don protective gloves, drop absorbent paper on spill.
   B. Dry Spills: Don protective gloves. Dampen area thoroughly taking care not to spread the contamination. Water may generally be used, except when chemical reaction with the water would generate an air contaminant; oil should be used instead.
5. Develope a decontamination plan and contact the Radiation Safety Officer.
6. A complete history of the accident and subsequent remedial or protective measures must be submitted to the Radiation Safety Officer.

9.4 INJURIES TO PERSONNEL INVOLVING RADIATION HAZARD (No other release)

1. Wash minor wounds immediately under running water, spreading the edges of the gash.
2. Report all radiation accidents involving personnel (wounds, overexposure, ingestion, inhalation) to the Radiation Safety Officer as soon as possible.
3. Call at once a physician qualified to treat radiation injuries.
4. Permit no person involved in a radiation injury to return to work without the approval of the attendant physician and the Radiation Safety Officer.
5. Prepare a complete history of the accident and subsequent activity related thereto for the Radiation Safety Officer.

9.5 DECONTAMINATION TECHNIQUES

Separate decontamination procedures are needed for personnel and areas. In cleaning objects and areas, the initial step depends on whether the contaminant is in powder or liquid form. If the material is dry or powdered, vacuuming is a most valuable technique, since much adherent material can be removed, lessening the chance for penetration into the surfaces when wetting agents are applied. A suitable method of filtration of effluent air from the vacuum cleaner must be provided, so that there is no further spread of radioactivity. Damp wiping and mopping with water and detergent are the next steps. If the chemical characteristics of the contaminant are not known, detergents of neutral pH are preferable to soaps, which - in some instances - may cause fixation of certain nuclides rather than removal. Complexing agents, e.g., citric acid or chelating agents (EDTA or DTPA) in combination with detergent or soap increase the cleaning efficiency; the action of chelating agents is accelerated by warming. Occasionally, dilute hydrochloric or nitric acid may be of value. The steps for decontamination are given below.

9.6 AREA DECONTAMINATION

Preoperational

1. Plan the decontamination operation thoroughly, and obtain supplies.
2. Provide adequate protection for all decontamination personnel, and allow for replacements.
3. Provide safe storage of all radioactive wastes and decontamination supplies.

Operational

1. Always work towards the center of contamination.
2. Take care not to spread or track contamination to cleaner (lower activity) areas.
3. Monitor frequently and thoroughly.
4. Cover clean areas with plastic sheets, kraft paper, or its equivalent.
5. Monitor all personnel and materials before permitting their movement to clean areas.

Postoperational

1. Quarantine all used cleaning solutions and decontamination equipment until they can be monitored.

9.7 PERSONNEL DECONTAMINATION

1. Lifesaving medical care always takes precedent over decontamination.
2. If the victims medical condition and your first aid knowledge allow, decontaminate wounds first and cover them with sterile waterproof dressings.
3. Wash the contaminated area with mild soap and water taking care to wash away from wounds.
4. If residual contamination is too high after step 3 you may proceed with mild abrasives such as corn meal or pumice loaded soap (Lava). Be certain not to break the skin.
5. As a last resort, potassium permanganate solution may be used.
6. Sweating out by enclosing the contaminated area in plastic bags or rubber gloves may be useful for uninjured personnel.

9.8 FIRES AND OTHER MAJOR EMERGENCIES

It is difficult for fire and police officials to evaluate accurately the magnitude of a radiation risk at the time of an emergency so we have posted entryways with emergency notification telephone numbers.

1. Notify all other persons in the room and building at once.
2. Notify the fire department and other local plant safety personnel as well as the Radiation Safety Officer.
3. Attempt to put out fires by approved means if radiation hazard is not immediately present.
4. Govern fire fighting or other emergency activities by the restrictions issued by the Radiation Safety Officer. Avoid, if possible, the tracking of contamination or passing of contaminated equipment into clean areas by emergency workers.
5. Monitor all persons involved in combating the emergency.
6. Following the emergency, monitor the area and determine the protective devices necessary for safe decontamination.
7. Decontaminate, follow a plan.
8. Permit no person to return to work without the approval of the Radiation Safety Officer.
9. Prepare a complete history of the emergency and subsequent activity related thereto for the Radiation Safety Officer.

10.0 ACTION LEVEL TABLE

1. The following may be dealt with in an informal manner (corrective action taken without the need to directly involve the Radiation Safety Officer or file a detailed report) and records of the actions taken need not be kept.

   a. Removable contamination (wipe test result) up to 2,000 DPM per 100 sq. cm.
   b. Spills in restricted areas up to 10 times the quantities listed in Appendix C of 10 CFR 20.
   c. Spills in unrestricted areas up to the quantities listed in Appendix C of 10 CFR 20.
   d. Unplanned releases of volatile radioactive material which if averaged over a 24 hour period would not exceed the concentrations listed in Table 2 of Appendix B to 10 CFR 20.

2. The following events require notification of Radiation Safety staff and documentation of the actions taken. Please use the appropriate form.

   a. Removable contamination (wipe test results) above 2,000 DPM per 100 sq. cm.
   b. Spills exceeding the amounts in 1.b. or 1.c. above.
   c. Unplanned releases of radioactive material larger than those in 1.d. above.
   d. Equipment contamination exceeding 5 mrem/hr or personnel contamination exceeding 2 mrem/hr.
   e. Personnel contamination which can not be reduced below 0.2 mrem/hr.

10.1 QUANTITIES LISTED IN APPENDIX C OF 10 CFR 20

Radioisotope	Activity
3-H	1,000 uCi
14-C	100 uCi
32-P	10 uCi
33-P	100 uCi
35-S	100 uCi
51-Cr	1,000 uCi
125-I	1 uCi

10.1 RELEASE QUANTITIES *

Radioisotope	Activity	Radioisotope	Activity
3-H	2.7 mCi	14-C	81 uCi
32-P	27 uCi	33-P	108 uCi
35-S	540 uCi	51-Cr	810 uCi
125-I	8 uCi		

*- Release quantities are the amounts of a single radioisotope which could typically be released into a 4000 cubic foot room having 10 air changes per hour without exceeding the Table 2 effluent concentration limits in a 24 hour period for an unrestricted area and are based upon a daily air flow of 2.7×10^{10} ml.

11.0 Radioactive Material Transfers

Transfer of radioactive material between licensees is allowed only in strict accordance with NRC and DOT regulations. Transfers from other than commercial sources must follow the same route as routine purchases. That is, prior approval from an authorized laboratory supervisor is required per Section 9.0 of this manual.

Outgoing shipments of radioactive material must be packaged, labeled, and monitored in accordance with all applicable NRC and DOT regulations. As with incoming shipments, prior approval from an authorized laboratory supervisor is required prior to shipping radioactive material.

Reminders: Antigen Express does not possess a license allowing the commercial distribution of radioactive material, nor do we have a license allowing the distribution of exempt concentrations to generally licensed individuals. The transfer of licensed material requires that a copy of the recipient's license be in the possession of the shipping licensee.

12.0 Bioassays

Bioassays as outlined below are required for any individual(s) who handles unsealed radioactive material in quantities meeting or exceeding those listed in Table 1 (below). For radioiodines, bioassays are required for any individual(s) handling quantities meeting or exceeding those listed in Table 1 of Regulatory Guide 8.20. Bioassay service is available to employees working with smaller quantities, and shall be required for employees working with smaller quantities if the nature of the work indicates an unusually high risk of of intake. Table 2 (below) shows the maximum allowable annual intake per 10 CFR 20. It is anticipated that intakes will stay well below these limits.

Table 1

Nuclide	Activity (mCi)
32-P	50
35-S	50
33-P	50

Table 2

Nuclide	Annual Limit On Intake (uCi)
3-H	80,000
14-C	2,000
32-P(oral)	600
33-P(oral)	6,000
35-S(oral)	10,000
51-Cr(inhal)	20,000
125-I(NALI) inhal	60

Notes on Table 2- These are intake limits not uptake limits. As an example, a thyroid burden of 0.6 uCi of 125-I 24 hours after intake would indicate an intake of 3 uCi if one assumes a 20% 24 hour uptake. See Table 3 (below) for fractional uptakes from inhaled intakes.

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Table 3

Nuclide	Fractional Uptake
32-P	0.8
35-S	0.8
125-I	0.2 (Thyroid @ 24 hours)

12.1 Methods

With the exception of 125-I bioassays will be perfcrmed by counting urine specimens in a calibrated liquid scintillation counter using the automatic external standard mode. Body burdens and intakes will be estimated by the methods in NUREG/CR-4884 which is incorporated by reference into this manual. 125-I bioassays will be performed by monitoring thyroid burdens of radioiodine.

12.2 Specific Methods for 32-P, 33-P, 51-Cr, 35-S,

Supplies and Equipment

1. Urine specimen delivered 24 hours after handling threshold limit of the radioisotope in question
2. 20 ml scintillation vials
3. Water accepting cocktail
4. Urine specimen from an individual not exposed to radioactive material
5. Automatic pipetters and disposable tips
6. Gloves and lab coat
7. Calibrated Liquid scintillation counter and quench correction curves
8. Calculator
9. Bioassay record forms

Procedure

1. Prepare a background vial containing 1 ml of sample from item 4. (above) plus 15 ml of cocktail.
2. Prepare a vial containing 1 ml of sample from item 1. plus 15 ml of cocktail.
3. Count both for 10 minutes.
4. Perform calculations as indicated on the record form and notify the RSO of results indicating an intake.

NOTE: 51-Cr may be counted in a "gamma counter" with a 3 inch NaI crystal at about 7% efficiency. Liquid scintillation counting of the electron may provide 50% efficiency.

12.3 Specific Method for 125-I

Supplies and Equipment

1. Calibrated Ludlum Model 12 rate meter with 44-3 probe

2. Bioassay record forms

Procedure

1. Check the background level in the area. Typically these measurements cannot be made in a restricted area because of the high sensitivity of the instrument. Background should not exceed 500 CPM.

2. Monitor the individuals thyroid by placing the probe in contact with the individuals neck over the thyroid. There is considerable individual variation in the anatomical location of the thyroid and care must be taken to monitor a large enough area paying particular attention to the region just above the articulation of the sternum and the clavicles.

3. Record the results of the assay on the record form and notify the RSO of all detectable thyroid burdens.

12.4 Interpretation of Bioassays

NUREG/CR-4884 allows one to calculate intakes from uptakes. The methods spelled out in this publication are to be used unless there is clear and convincing evidence that because of unique metabolic circumstances they may not be accurately applied. An example of this situation might be an individual who is known to be hypothyroid or hyperthyroid. A series of bioassays will be needed in these cases and follow-up bioassays will be required in all cases in which there is an indication that an intake exceeding 10% of an ALI has occurred.

13.0 The following section of this manual contains forms and instructions for completing same.

ANTIGEN EXPRESS 125-IODINE BIOASSAY RECORD

DATE	INDIVIDUAL MONITORED	INSTRUMENT	BACKGROUND	THYROID	NETnCi	BY

NOTE: Unless otherwise noted all measurements are made with a Ludlum Model 12 rate meter equipped with a Model 44-3 probe calibrated so that 1 nanocurie of 125-I results in 50 CPM through 3/8" tissue equivalent material.

ANTIGEN EXPRESS BIOASSAY RECORD FORM

For 32-P, 33-P, 35-S, 51-Cr

Individual_____

Urine Specimen Delivered On_____(Date & Time)

After Handling _____mCi of_____ On_____(Date & Time

Volume Counted _____ ml On_____(Date)

NET CPM In Sample_____ At _____% efficiency yields

NET DPM In Sample_____ which is _____uCi.

uCi in sample/liters in sample = _____ uCi per liter

Mass of Individual _____ Kgm

Elapsed time _____hours (intake to sample)

Urine produced during that time (0.8ml/Kgm/hour)_____ml

Estimated Total Activity in urine since intake_____ uCi

Fraction of initial intake during elapsed time _____(NUREG/CR-4884

Estimated Intake_____uCi

Is a follow-up specimen required ? Yes No

Calculations performed by_____

ANTIGEN EXPRESS INVENTORY PROCEDURES

Assumptions

1. All radioactive material is received on the last day of each month.

2. All months are 30 days long.

Caution: This method greatly simplifies keeping an inventory, but may overstate 32-P inventories by a factor of 2 and may overstate 125-I inventories by a factor of 1.4.

Procedure

1. Fill out an "Individual Shipment Inventory Sheet" for each shipment of radioactive material.

2. Perform a 30 day decay on the previous month's totals.

3. Add the material received during the preceding month to the results obtained in step 2.

4. The results obtained from step 3 are the totals as of the end of the preceding month.

5. Because this method overstates inventory amounts, during January a physical inventory of working stock and waste should be performed to bring the totals to their correct amounts.

ANTIGEN EXPRESS INDIVIDUAL SHIPMENT INVENTORY SHEET

Received on _____ date

Radioisotope _____

Quantity _____ mCi

Concentration _____ mCi/ml

Chemical Form _____

BE CERTAIN THAT THE RADIOISOTOPE RECEIVING FORM IS COMPLETE

DATE	REMOVED		REMAINING	
	Volume (ml)	Activity (mCi)	Volume (ml)	Activity (mCi)

ANTIGEN EXPRESS RADIOACTIVE MATERIAL INVENTORY

For the month of _____

Radioisotope	Preceding Total mCi	30 Day Decay Factor	Decayed Total	Received mCi	New Total mCi
32-P		0.2336			
33-P		0.435			
35-S		0.7895			
51-Cr		0.472			
125-I		0.7071			

License limits:

ANTIGEN EXPRESS RADIOACTIVE MATERIAL INVENTORY

For the month of _____

Radioisotope	Preceding Total mCi	30 Day Decay Factor	Decayed Total	Received mCi	New Total mCi
32-P		0.2336			
33-P		0.435			
35-S		0.7895			
51-Cr		0.472			
125-I		0.7071			

License limits:

ANTIGEN EXPRESS RADIOACTIVE MATERIAL INVENTORY

For the month of _____

Radioisotope	Preceding Total mCi	30 Day Decay Factor	Decayed Total	Received mCi	New Total mCi
32-P		0.2336			
33-P		0.435			
35-S		0.7895			
51-Cr		0.472			
125-I		0.7071			

License limits:

ANTIGEN EXPRESS RADIOISOTOPE RECEIVING FORM

Instructions

1. Treat all incoming shipments of radioactive material as contaminated. Wear gloves and lab coats for this procedure.

2. Perform this procedure in a low background area. The background should be 0.05 mrem per hour or lower.

3. Visually inspect the package for signs of damage or leaks. If there are any indications that the integrity of the inner container has been broached, halt the check-in and notify radiation safety staff.

4. Wipe the outside of the package with a piece of paper and check the paper with a thin end-window Geiger counter. If readings above background are noted halt the check-in and notify radiation safety staff. The Radiation Safety Officer will quantitate the activity and notify the shipper, carrier, and NRC if the limits in 10 CFR 20.205 are exceeded.

5. Using a thin end-window Geiger counter monitor the radiation dose rates at one meter from and at contact with the outer surface of the package. If the dose rate at one meter exceeds 10 mrem per hour or the dose rate at contact exceeds 200 mrem per hour halt the check-in and notify radiation safety staff.

6. Using a thin end-window Geiger counter monitor the radiation dose rate at contact with the primary container. Treat lead pigs provided by the vendor as the primary container.

7. Record the results of the check-in in the appropriate locations on the back of this sheet.

8. Fill out an "Individual Shipment Inventory Sheet".

9. Before disposing of boxes confirm they are not contaminated using a thin end-window Geiger counter and remove or deface all "radioactive" labels.

Check-in Data

Radioisotope_____ Quantity_____mCi

Date Received_____ Purchase Order_____

NOTE: If the contents indicated on the packing slip are not what was ordered do not open the package. Immediately notify the Radiation Safety Officer.

Visual Inspection OK NOT OK (circle one)

Wipe Results OK NOT OK (circle one)

Radiation Dose Rates

One Meter_____mrem/hour

Contact_____mrem/hour

Check-in performed by _____

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This section is to be completed only by Radiation Safety and only for shipments which fail the initial check-in.

Net DPM on surface wipe is _____ DPM/100 cm^2

Contact dose rate is _____ mrem/hr

T.I. is _____ mrem/hr

The RSO will notify the NRC, transporter, and shipper of contamination or dose rates in excess of limits.

ANTIGEN EXPRESS DECAYED RADIOACTIVE WASTE DISPOSAL RECORD

Radioisotope	Original Amount	Storage Date	Disposal Date	Survey Data Background	Waste	Instrument	By

ANTIGEN EXPRESS DECAYED WASTE DISPOSAL PROCEDURE

1. Only radioactive waste with a half-life shorter than 100 days may be disposed of in this manner.

2. Disposal surveys are to be performed only by radiation safety staff.

3. Records of each disposal are to be entered on the appropriate form.

4. Surveys are to be made in low background (0.05 mrem/hour) areas only.

5. All labels indicating that the material was radioactive are to be removed or defaced prior to disposal as regular waste.

6. The date of the last addition to waste put into storage for decay to background levels shall be recorded on each container. The container shall also be labeled with the radioisotope(s) present and the initial quantity of each.

7. If dose rates above background are noted the waste shall be returned to storage for at least 2 half-lives prior to re-survey.

ANTIGEN EXPRESS LIQUID RADIOACTIVE WASTE SINK DISPOSAL INSTRUCTI

1. Sink disposal is allowed only for liquid waste which is readily dispersib in water.

2. Only the designated radioactive waste disposal sink may be used for liquid radioactive waste disposal.

3. At the time of disposal the concentrations at the trap must be at or belo those concentrations tabulated below.

4. Start the water running at a rate just short of the splash point. This will be 5 to 10 liters per minute and if necessary dilution factors may be calculated for the 5 liters per minute rate. The important point is t wet the sink and pipes so as to minimize sticking problems.

5. Slowly pour the waste directly into the drain.

6. Let the water run for another 5 to 10 minutes to clean the sink and pipes

7. Record each disposal on the Radioactive Waste Sink Disposal form.

8. Before the tenth of each month total the preceding month's sink disposal and adjust the Inventory Total accordingly. Before the tenth of January an annual total should be tallied from the monthly totals and recorded in the appropriate location on the preceding Decembers Radioactive Sink Disposal form.

9. If concentration limits allow annual totals may reach but not exceed thos listed below. Please note that the license possession limits will typically prevent exceeding annual limits.

MONTHLY SINK DISPOSAL CONCENTRATION LIMITS

Nuclide	Concentration (uCi/liter)
3-H	10
14-C	0.4
32-P	0.09
33-P	0.8
35-S	1
51-Cr	5
125-I	0.04

NOTE: In spite of concentration limits, not more than 5 Ci of 3-H, 1 Ci of 14-C and a total of1 Ci of all other licensed material may be disposed of in this manner.

ANTIGEN EXPRESS RADIOACTIVE WASTE SINK DISPOSAL RECORD

Month December Year _____

Date Of Disposal	Radioisotope	Activity Microcuries	Concentration Microcuries/l
MONTHLY TOTALS			

Annual Totals (mCi) 32-P 35-S 125-I

_____ _____ _____

ANTIGEN EXPRESS RADIOACTIVE WASTE SINK DISPOSAL RECORD

Month _____ Year _____

Date Of Disposal	Radioisotope	Activity Microcuries	Concentration Microcuries/l
MONTHLY TOTALS			

ANTIGEN EXPRESS, INCORPORATED

RADIATION SAFETY

DECLARED PREGNANT WOMAN FORM

I, _____ voluntarily inform you of my pregnancy and
(name-please print or type)
the estimated date of conception _____. I understand that to comply with the radiation exposure limits set in 10 CFR, Part 20.1208 and/or 105 CMR 120.218, it may be necessary to modify my working conditions for the duration of my pregnancy.

Date _____ **Signature** _____

BY ORDER OF THE U.S. NUCLEAR REGULATORY COMMISSION

NOTICE TO ALL PERSONNEL OF

ANTIGEN EXPRESS, INC.

Current copies of the following documents are available from the Radiation Safety Officer.

1. Title 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections.

   ("Regulations in this part establish requirements for notices, instructions and reports by licensees to individuals participating in licensed activities, and options available to such individuals in connection with Commission inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, and regulations, orders, and licenses issued thereunder regarding radiological working conditions.")

2. Title 10 CFR Part 20, Standards for Protection Against Radiation

   ("The regulations in this part establish standards for protection against radiation hazards arising out of activities under licenses issued by the Nuclear Regulatory Commission.....")

3. ANTIGEN EXPRESS, Inc's. Byproduct Material License, all license conditions, and amendments and all correspondence pertaining to such license.

123358

OFFICIAL RECORD COPY ML 10

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: _

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ANTIGEN EXPRESS, INC.
RECEIVED DATE: 960624
DOCKET NO: 3034182
CONTROL NO.: 123358
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $1500.00
CHECK NO.: 348

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 6/26/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /✓/)

1. FEE CATEGORY AND AMOUNT: 3M $1,500

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE /

3. OTHER _____

SIGNED B Brown
DATE 7/3/96

I (96)
Log July 2
Reviewer
Check No 348
Amount $1,500
Fee Category 3M
Type of Fee APP
Date Check Rec'd 7/3/96
Date Completed 7/3/96
By B Brown