

MATERIALS LICENSE

Amendment No. 01

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.

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Licensee

1. Apollon, Incorporated

2. Great Valley Corporate Center
One Great Valley Parkway
Malvern, Pennsylvania 19355-1307In accordance with the letter dated
July 23, 1996,3. License Number 37-28782-01 is amended in
its entirety to read as follows:

4. Expiration Date March 31, 2003

5. Docket or
Reference No. 030-328926. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Hydrogen 3
B. Carbon 14
C. Phosphorus 32
D. Phosphorus 33
E. Sulfur 35
F. Chromium 51
G. Iodine 125A. Any
B. Any
C. Any
D. Any
E. Any
F. Any
G. AnyA. 100 millicuries
B. 40 millicuries
C. 50 millicuries
D. 50 millicuries
E. 75 millicuries
F. 30 millicuries
G. 50 millicuries

9. Authorized use

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

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at One Great Valley Parkway, Malvern, Pennsylvania.

11. A. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, Leslie Coney, Ph.D., Terry Higgins, Ph.D., C. Satishchandran, Ph.D., Khushroo Shroff, Ph.D., Felicia Watson and Daniel McCallus, Ph.D. Licensed material listed in Item 6 above, except iodine-125, is authorized for use by, or under the supervision of, Richard Ciccarelli, Ph.D., Malcolm Montgomery, Ph.D., Kathleen Herold, Catherine Pachuk, Ph.D. and Donald Sims, Ph.D.

B. The Radiation Safety Officer for this license is Linda Snyder, Ph.D.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

37-28782-01

Docket or Reference Number

030-32892

Amendment No. 01

12. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
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 65 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."
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 August 4, 1992
 - B. Letter dated November 10, 1992
 - C. Letter dated July 23, 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Richard Gibson

Date SEP 23 1996

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

SEP 23 1996

Linda Snyder, Ph.D.
Radiation Safety Officer
Apollon, Incorporated
Great Valley Corporate Center
One Great Valley Parkway
Malvern, Pennsylvania 19355-1307

Dear Dr. Snyder:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

Your amended license has been written in a new format that incorporates current regulatory requirements and NRC policy. Because radioactive waste disposal sites are available at the present time, Condition 15 of your license is not necessary and has been deleted from your amended license. However, should such sites become unavailable to you in the future, you will be required to resubmit your interim waste storage plan. Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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.

Thank you for your cooperation.

Sincerely,
ORIGINAL SIGNED BY:

Richard Gibson, Jr.
Division of Nuclear Materials Safety

License No. 37-28782-01
Docket No. 030-32892
Control No. 123493

Enclosure:

Amendment No. 01

DOCUMENT NAME: R:\WPS\MLTR\L3728782.01

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	<input checked="" type="checkbox"/>	N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	RGibson/rxg							
DATE	09/11/96			09/ /96		09/ /96		09/ /96

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Apollon

ms-16
J2

FACSIMILE FORM

TO: Richard Gibson

FIRM: NRC

FAX NO.: 337-5368

FROM: Linda Snyder, RSO

SENDER'S FAX NO.: 610-647-9732

DATE: 8-2-96

TIME: 10:30 AM

TOTAL NUMBER OF PAGES (INCLUDING COVER PAGE): 2

IF YOU HAVE ANY QUESTIONS, PLEASE CALL: 610-647-9452

* * * * *

MESSAGE: Mr. Gibson - Attached is a revised training form for

Don McCallis. He has a total of 4 years experience working

with isotopes. He initially filled out the form thinking that

his experience at Apollon was the only relevant information needed.

Linda Snyder

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERY OF THE MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE. THANK YOU.

Apollon, Inc. • One Great Valley Parkway • Malvern, Pennsylvania 19355-1423 • Telephone (215) 647-9452 • Facsimile (215) 647-9732

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Name: Daniel E. McCallusDate: 8/2/96

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	U. of PA	2 hr	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No
	Apollo Inc	1 hr		
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	Same	Same	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Same	Same	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No
d. Biological effects of radiation.	Same	Same	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^{35}S	250 μCi	Apollo Inc	2 years	protein labelling
^{32}P	500 μCi	U. Penn	2 years	DNA labelling
^{14}C	250 μCi	U. Penn	2 years	protein labelling

123493

TELEPHONE CONVERSATION RECORD	Date: August 1, 1996	Time: 2:09 pm
Mail Control No.: 123493	License No. : 37-28782-01	Docket No.: 030-32892
Person Called: Linda Snyder, Ph.D.	Organization: Apollon, Inc.	Telephone Number: 610-647-9452
Person Calling: Richard Gibson Jr.		
Subject: Licensing action/amendment, letter dated July 23, 1996		
<p>Summary: 1. With regard to Daniel McCallus, Ph.D., submit additional training and on-the-job experiences with radioisotopes in his graduate and undergraduate studies. Do you wish for him to be authorized for all radioactive material on the license? Dr. Snyder stated that she will get that information for me and that they do wish for Dr. McCallus to be authorized for all the radioactive material on the license. In addition, Richard Ciccarelli, Ph.D., Malcolm Montgomery, Ph.D., Catherine Pachuk and Donald Sims are not authorized to use iodine-125.</p>		
Action Required/Taken: submit additional information		
Signature: Richard Gibson, Jr.	Date: August 1, 1996	



Apollon

030-32892

July 23, 1996

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

To Whom It May Concern:

Apollon, Inc. is applying for an amendment to material license number 37-28782-01. I have enclosed two copies of the amendment application and a license fee of \$590.

If you have any questions regarding this amendment, please feel free to call Dr. Leslie Coney or myself at (610) 647-9452. Thank you for your consideration of this matter.

Sincerely,

Linda A. Snyder
Linda A. Snyder, Ph.D.

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123493

JUL 25 1996

(10-84)

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

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

1. THIS IS AN APPLICATION FOR (Check appropriate item)		2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)	
<input type="checkbox"/> A. NEW LICENSE		Apollon, Incorporated Great Valley Corporate Center One Great Valley Parkway Malvern, PA 19355-1307	
<input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>37-28782-01</u>			
<input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____			
3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION	
Apollon, Incorporated Great Valley Corporate Center One Great Valley Parkway Malvern, PA 19355-1307		Leslie Coney Ph.D.	
		TELEPHONE NUMBER (610) 647-9452	
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.			
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED	
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE		8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS	
9. FACILITIES AND EQUIPMENT		10. RADIATION SAFETY PROGRAM	
11. WASTE MANAGEMENT		12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3.M</u> AMOUNT ENCLOSURE \$ <u>590</u>	
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.			
CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE Vincent R. Zurawski, Jr President and CEO		SIGNATURE  DATE <u>19 JUL 96</u>	

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

OFFICIAL RECORD COPY

ML 10

123493

JUL 25 1996

NRC LICENSE NO. 37-28782-01 AMENDMENT NO. 1

This document contains the attachments to Form 313 applying for an amendment to NRC License No. 37-28782-01 for:

Apollon
Great Valley Corporate Center
One Great Valley Parkway
Malvern, PA 19355

The application for amendment has been prepared in response to a need to increase possession limits for certain isotopes; to list and delist authorized users; and to incorporate revisions to 10 CFR 20 "Standards for Protection Against Radiation." Based on an evaluation of 10 CFR 30.15 requirements and the increased possession limits requested by this amendment, Apollon is still exempt from having to secure financial assurance funding for decommissioning.

Form 313, Item 5: Radioactive Material

Chemical and/or Maximum Amount to be
Element and Mass Physical Form Possessed at Any One Time

1.	carbon-14	Any	40 mCi
2.	chromium-51	Any	30 mCi
3.	hydrogen-3	Any	100 mCi
4.	iodine-125	Any	50 mCi
5.	phosphorus-32	Any	50 mCi
6.	phosphorus-33	Any	50 mCi
7.	sulfur-35	Any	75 mCi

The above table is requesting possession limit changes for Cr-51 from 20 mCi to 30 mCi; H-3, from 75 mCi to 100 mCi; S-35, from 50 mCi to 75 mCi; and adding 50 mCi of P-33 which was not previously listed.

Form 313, Item 6: Purposes for which Licensed Material will be Used
(No change. The same as submitted on original license application)

Form 313, Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

1. Linda Snyder, Ph. D.,
Principal Research Scientist

Dr. Snyder will serve as Radiation Safety Officer, replacing Dr. Leslie Coney.

Dr. Snyder has fourteen years experience using radioactive materials and has received 17 hours of training including 10 hours formal radiation safety classroom training in 1993 from the RSO for her employer at the time, Sterling Winthrop, Inc.; a two hour formal course at the University of Pennsylvania in 1987; a four hour formal course at Princeton University in 1988; and one hour formal training from her present employer, Apollon, Inc., in 1995.

Dr. Snyder is scheduled to attend a 3-day comprehensive RSO training course conducted by Engelhardt & Associates from July 29- 31, 1996.

2. Leslie Coney, Ph.D.
Associate Director for Business Development

Dr. Coney will serve as a back-up Radiation Safety Officer in the event Dr. Snyder is unavailable. Dr. Coney has 16 years of experience using radioactive materials and has been the RSO for Apollon for the past four years

Eight additional persons are requested to be authorized to use and/or directly supervise the use of radioisotopes. Their training and experience forms are attached (Appendix I).

3. Richard Ciccarelli, Ph.D.
V.P. of Biologics and Pharmaceuticals Research
4. Terry Higgins, Ph.D.
Senior Director, Immunobiology and Clinical Immunology
5. Daniel McCallus, Ph.D.
Senior Research Scientist
6. Malcolm Montgomery, Ph.D.
Senior Analytical Scientist

7. C. Satishchandran, Ph.D.
Assistant Research Fellow
8. Khushroo Shroff, Ph.D.
Senior Research Scientist
9. Donald Sims, Ph.D.
Director, Analytical R&D and Q.C.
10. Felicia Watson
Principal Analytical Research Associate

Kathleen Herold and Catherine Pachuk, Ph.D., who are currently listed on the license, are to remain listed.

David Sanborn, Ray Boutin, Kyonggeun Yoon, and Meiqing Lu who are also currently listed on the license as authorized users are to be removed from the license.

In addition to the personnel listed above, we are discontinuing the consulting arrangement Jean-Claude Dehmel and establishing a new arrangement with George W. Moncrief of George Moncrief and Associates, West Chester, PA to assist with our radiation safety program. Mr. Moncrief's curriculum vita is included in Appendix I.

Form 313, Item 8: Training for Individuals Working in or Frequenting Controlled Areas

(No change. The same as submitted on original license application.)

Form 313, Item 9: Facilities and Equipment

The following description of facilities has been revised to reflect the latest definitions of "Controlled" and "Restricted" areas as contained in the September 29, 1995 issue of the 10 CFR Part 20 regulations.

Apollon has designated certain labs as Controlled Areas and has isolated certain other areas as Restricted Areas. The labs marked with yellow ink on the maps provided in Appendix III (maps 2, 3, and 4) of the original license application are posted "Caution - Radioactive Materials" and are considered "Controlled" areas. These areas will have exposure levels suitable for protection of the general public. They contain shielding appropriate for the radioisotopes being used, survey meters and counters appropriate for the radioisotopes being used, absorbent paper for covering bench tops, and disposable gloves.

The waste disposal barrel collection area shown in orange on the maps in Appendix III of the original license application is now considered a "Restricted" area and may not always have

exposure levels suitable for the general public. This area will be posted "Restricted Area, Authorized Entry Only."

Iodinations are not currently being performed but if iodinations were to be performed in the future, they would be conducted in the fume hood designated for this purpose and marked in green ink on Appendix III of the original license application. The iodination area would be posted, "Restricted Area, Authorized Entry Only." The fume hood used for iodination would be arranged and outfitted as described in the original license application.

Emergency equipment:	(No change. Same as submitted on original license application)
Equipment listing:	(No change. Same as table found in Appendix IV of original license application).

Form 313, Item 10: Radiation Safety Program

1.0 - 1.5 Radiation Safety Program

It is proposed to amend the Radiation Safety Program described in the original license application as follows:

Delete the sentence in subsection 1.5.1 stating "It will be the responsibility of the RSO to see that all incidents or accidents are immediately reported to the NRC " and replace it with the following sentence:

"It will be the responsibility of the RSO to see that incidents or accidents are reported to the NRC as required by 10 CFR 20.2201- .2205, Subpart M and are followed up with written reports within 30 days."

2.0 Radiation Dosimetry Program

It is proposed that this section of the originally submitted radiation dosimetry program be amended to replace references to 10 CFR 20.101 and 10 CFR 20.103 with 10 CFR 20.1201 through 20.1204.

2.1 External Radiation Dose

Proposed amendments to this section are:

- a) Exchange film and thermoluminescent whole body and finger badges quarterly instead of monthly. For declared pregnant workers, badges will continue to be exchanged monthly.

- b) Replace references to 10 CFR 20.401, .403, .405, .407 and .408 with 10 CFR 20.2101 through 20.2206.

2.2 Internal Radiation Exposure

The bioassay program will remain essentially as submitted in the original application except that before a new user begins to work with radioisotopes, a user's potential for exceeding 10% of an allowable annual internal dose will be assessed. Persons likely to receive 10% of an allowable annual internal dose will be placed into the bioassay program in which urine analyses and thyroid scans, as appropriate, will be performed as described in the original application.

The criteria for determining if a person should be in a bioassay program will be based on the following quantities of use:

- a) >100 mCi single use or cumulative monthly use of H-3, C-14, P-32, P-33, S-35 or Cr-51 used in a laboratory hood,
- b) >10 mCi single use or cumulative monthly use of H-3, C-14, P-32, P-33, S-35 or Cr-51 not in a laboratory hood.
- c) >0.1 mCi single use or cumulative monthly use of inorganic forms of I-125 in the iodination hood.
- d) >1.0 mCi single use or cumulative monthly use of organically bound forms of I-125 in or outside of a laboratory hood.

2.3 Surveillance

In accordance with the request to amend the dosimetry program from monthly to quarterly, the RSO responsibilities to monitor and evaluate external exposures is proposed to be amended to quarterly instead of monthly.

3.0 Environmental Release Evaluation

Small amounts of radioactive materials discharged as aqueous liquid waste to the sanitary sewer will be maintained well within the monthly and annual limits set forth in Table 3 of Appendix B to 10 CFR, Part 20.

3.1 Liquid Effluents

The average monthly sanitary sewer effluent is typically 75,000 gallons. The allowable monthly activity discharged to the sanitary sewer from the Apollon site has been calculated from the concentration limits in Appendix B of 10 CFR Part 20, a sewer effluent flow rate of 75,000 gallons per month and a safety factor of 10 as shown in the table below. Simplified conservative rules will be established for individual users from these table values and the number of users of a given nuclide.

SANITARY SEWER DISPOSAL LIMITS

Readily Soluble or Dispersible Form of:	Monthly Site Effluent Activity Limit (Note 1)	Adjusted Effluent Activity Limit (Note 2)
H-3	284 mCi (Note 3)	$284(F/75000)$ mCi
C-14	8.53 mCi (Note 4)	$8.53(F/75000)$ mCi
P-32	2.56 mCi (Note 5)	$2.56(F/75000)$ mCi
P-33	22.7 mCi (Note 5)	$22.7(F/75000)$ mCi
S-35	28.4 mCi (Note 5)	$28.4(F/75000)$ mCi
Cr-51	142 mCi (Note 5)	$142(F/75000)$ mCi
I-125	0.57 mCi (note 5)	$0.57(F/75000)$ mCi

Notes to table:

1. Based on normal sewer effluent of 75,000 gallons per month and then reduced further by a safety factor of 10.
2. Adjust by substituting actual flow in gallons per month for F if substantially different from 75,000 gallons/month.
3. Annual H-3 limit of 5 Ci cannot be attained at this monthly rate.
4. Annual C-14 limit of 1 Ci cannot be attained at this monthly rate.
5. The "Sum of Fractions" rule will be used to project compliance with the P-32, P-33, S-35, Cr-51, and I-125 combined annual limit of 1 Ci. User's monthly sanitary sewer disposal limits will be reduced accordingly if projections indicate the 1 Ci limit could be attained.

3.2 Gaseous Effluents

Small quantities of the more volatile forms of radio nuclides H-3, C-14 and I-125 which may become airborne during the conduct of research activities will be well below 10 CFR Part 20, Appendix B, Table 2 limits. It is requested that the language in the original license application be amended to require grab and/or continuous sampling of airborne effluents to unrestricted areas only during iodinations in the iodination hood.

4.0 Radiological Sampling and Monitoring

Radiological sampling and monitoring surveys to assess radiation levels, concentrations or quantities of radioactive material and potential hazards from handling radioactive materials will be performed in accordance with the requirements of 10 CFR 20.1501 as follows:

4.1 External Radiation Exposures

External exposure radiation surveys will be conducted in areas where exposure rates exceed allowable dose limits in 10 CFR 20.1201, .1207, .1208, and .1301.

4.2 Airborne Concentrations

The presence and concentration of airborne radioactive materials will be monitored with air samplers whenever operations could expose personnel above 25% of the limits specified in Table 1, Column 3, Appendix B to 10 CFR Part 20.1001-20.2401.

4.3 Surface Contamination

Routine surface contamination surveys will be conducted throughout each radiologically controlled area and also in the adjacent areas which are not radiologically controlled. Surface contamination surveys include both removable and fixed contamination. Survey frequencies will be conducted as follows:

- a) Weekly in all Controlled Areas and designated uncontrolled areas adjacent to Controlled Areas.
- b) Weekly surveys will be conducted in Restricted Areas.
- c) At the end or completion of each research test or experiment which involves direct handling, dispensing, processing, or movement of radioactive materials in non-encapsulated forms.
- d) At the end of each day or shift whenever a process or test is anticipated to last more than one shift or day;

- e) Whenever it is known or suspected that an area or item is contaminated;
- f) Whenever it is known or suspected that personal clothing or skin is contaminated;
- g) Whenever elevated airborne concentrations have been detected;
- h) Whenever a spill has occurred; and
- i) Whenever deemed necessary by the RSO to supplement current survey frequencies.

All monthly and weekly survey results will be documented on survey forms. Survey forms completed by the research staff will be transmitted to the RSO for appropriate record keeping. Survey forms completed by the RSO will be maintained by the RSO with all other survey results.

Fixed and removable surface contamination surveys will be conducted as described in the original application but with the following amended statement regarding historical records of isotope use areas:

Except for areas containing only sealed sources that have not leaked or byproduct material with half-lives less than 65 days, a permanent record will be maintained and updated every 2 years listing, in a single document,:

- a) all areas designated as Controlled or Restricted as defined by 10 CFR 20.1003,
- b) any spill area or other contamination incident in which contamination may have remained after cleanup, or
- c) any area likely to have contamination that spread to inaccessible areas.

4.6 Survey of Packages Received and Prepared for Shipment

The external surfaces of all packages received at the receiving/shipping dock or staging area and labeled with a Radioactive White I, Yellow II or Yellow III DOT label (unless containing only byproduct material in gaseous form) will be surveyed for surface contamination to verify compliance with 10 CFR 20.1906.

All radioactive materials bearing "Yellow-II" or "Yellow-III" labels will be transported by cart to minimize personnel exposures. Incoming packages containing significant amounts of volatile or resuspendable radioactive materials will be inspected in fume hoods with adequate ventilation.

Except for packages containing quantities of radioactive material in excess of a Type A quantity as defined in 10 CFR 71.4 and Appendix A to part 71, White-I, Yellow-II or Yellow-III labeled packages will be monitored as soon as practical after receipt but not later than 3 hours after such a package is received during normal business hours or 3 hours after the start of the next business day if the package is received after normal working hours. For packages containing in excess of Type A quantities, arrangements will be made to either receive the package when it is offered for delivery or arrange for notifying the RSO when the carrier receives it at his terminal so that expeditious possession arrangements can be made.

All allowable surface contamination limits and radiation exposure rate limits remain as required by 10 CFR 71.87(I) and 10 CFR 71.47.

4.7 Radiation Posting, Labeling, and Control

The RSO will ensure that all Controlled and Restricted areas are properly posted and labeled in accordance with 10 CFR Parts 19.11, 19.12, and 20.1901-.1903.

All areas or rooms in which licensed material is used or stored in amounts exceeding 10 times the amounts in Appendix C to 10 CFR Part 20 will be posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

Containers of licensed material in quantities equal to or greater than the quantities listed in Appendix C, 10 CFR Part 20, or in concentrations equal to or greater than the concentrations specified in Table 3 of Appendix B, 10 CFR Part 20, will be labeled with the radiation symbol; the words, "CAUTION: RADIOACTIVE MATERIAL" or "DANGER: RADIOACTIVE MATERIAL "; the nuclide(s) present; the activity; and the date when the activity was determined.

4.8 Sealed Source Leak Tests

Sealed sources containing more than 100 mCi of beta-gamma emitting by-product materials with a half-life of more than 30 days will be leak tested at six month intervals in accordance with statements and procedures submitted with the original license application.

4.9 Exhaust Ventilation Survey and Testing

Fume hoods, glove boxes, and ventilated enclosures will be surveyed annually to verify that adequate ventilation face velocity is maintained at 100 fpm or more in

accordance with all statements and procedures submitted with the original license application.

5.0 Effluent Monitoring

Amendments to statements, procedures and representations made at the time of the original license application concerning exhaust stack monitoring are requested as follows:

5.1 Airborne Effluents

Radioiodine

Exhaust ventilation effluents will be continuously monitored for radioiodine emissions whenever iodinations are being performed. The selection of release points (hoods) and sampling system will be based on whether or not radioactive iodine is being used and the specific ventilation system features. The following description is typical of the approach used in monitoring and assessing airborne radioiodine releases.

A typical sampling system for radioiodine consists of the following components:

- a) A sampling probe is installed into the air duct past, i.e., downstream of the filter housing. The sampling probe is installed in a section of the ductwork where the air flow stream is the least disrupted. The diameter of the sampling probe is selected to provide near-isokinetic sampling for a range of anticipated system exhaust and sampling flow rates.
- b) A charcoal sample collection tube is connected as closely as possible to the sampling probe. The filter train consists of a particulate filter paper followed by an activated carbon cartridge. The filter train typically consists of a single unit equipped with quick disconnects to facilitate its periodic replacement.
- c) The sampling flow rate is measured by a calibrated flow rotameter. The range of the flow rotameter is adjustable to cover the range of anticipated system exhaust and sampling flow rates.
- d) The vacuum pump is the last component of the sampling system. The actual flow rate is set to the required setting to maintain near-isokinetic sampling conditions.

Sample analyses will consist of a gross beta or gamma counts absorbed on charcoal collection tubes. Predetermined gross beta and gamma count-rate action levels will be established above which more sophisticated analytical techniques will be used to identify specific radionuclides. Carbon cartridges will be directly analyzed for I-125 since this radionuclide will be used rather routinely.

The action level (for gross beta or gamma activity) will be derived by taking into account stack exhaust flow rates, sampling flow rates, anticipated sampling device collection efficiency, system counting efficiency, and applicable MPC. Based on a weekly replacement schedule, the anticipated activity on the carbon cartridge will be estimated assuming a 90% collection efficiency and selecting 10% rather than 25% of the MPC to account for sampling and counting uncertainties.

Any carbon cartridge which exceeds the specified action levels will be subjected to gamma spectroscopic analyses in order to identify the radionuclide(s). These analyses will be primarily performed in-house and, at times, by licensed commercial facilities for QA/QC purposes. Sample flow rates, sample volume, and counting times will be adjusted to reflect actual conditions and to ensure that the derived action levels can be met.

The results of the carbon cartridge analyses will be evaluated and compared against the dose limits for individual members of the public in 10 CFR 20.1301.

Other Nuclides

Other byproduct materials currently being used or anticipated to be used in the foreseeable future do not warrant airborne effluent monitoring. If the RSO, upon reviewing a proposed new use, finds that there is a potential for airborne emissions of a radionuclide other than I-125, the RSO will arrange for the necessary airborne effluent monitoring protocols to be developed and submitted as a separate amendment.

5.2 Liquid Effluents

No change except that analyses and predetermined action levels will be derived from Table 3, Appendix B, 10 CFR Part 20 as described above for releases into sanitary systems.

6.0 Radiological Surveillance

The radiological surveillance program is unchanged except for references to 10 CFR 20.205 and 10 CFR 20.311 in subsection 6.5.2, Radioactive Materials Receipt and Distribution which are changed to 10 CFR 20.1906 and 10 CFR 20.2006 respectively.

7.0 Emergency Preparedness

The emergency preparedness program remains as originally submitted except for references to 10 CFR, Parts 20.403 and 20.405 in subsection 7.2(c), Theft or Loss of Radioactive Materials, which change to 10 CFR 20.2202 and 10 CFR 20.2203 respectively and reporting requirements become as stated below:

Immediate notification:

- a) Any loss or theft of licensed material.
- b) Any event that may have caused or threatens to cause:
 - an individual to receive a total effective dose (TEDE) of 25 rems or more,
 - an eye dose equivalent of 75 rems or more, or
 - a shallow dose equivalent to the skin or extremities of 250 rads or more.
- c) The release of radioactive material so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (ALI)

Twenty-four hour notification:

- a) An individual received or could have received:
 - a TEDE of 5 rems over a 24 hour period,
 - an eye dose equivalent exceeding 15 rems, or
 - a shallow dose equivalent to the skin or extremities exceeding 50 rems.
- b) The release of radioactive material, such that had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (ALI).

Written notification, in addition to follow-up written reports for the above incidents, will be filed within 30 days after learning of the following occurrences:

- a) Received doses in excess of any allowable dose limit
- b) Levels of radiation or concentrations of radioactive material in excess of any allowable limit in a licensed restricted area, or in excess of 10 times any applicable limit in an unrestricted area.

Reports will contain all information requested in applicable portions of 10 CFR 20.2202 and .2203.

Form 313, Item 11: RADIOACTIVE WASTE MANAGEMENT

No changes in radioactive waste management procedures as submitted in original license application except:

1. References to 10 CFR 20.303 for sanitary sewer disposal are to be changed to 10 CFR 20.2003.
2. References to 10 CFR 20.306 for disposal of exempt concentrations of H-3 and C-14 scintillation fluids and animal carcasses are to be changed to 10 CFR 20.2005.
3. References to 10 CFR 20, Appendix B, Table 2, Column 2) for volatile and gaseous wastes that may be discharged into the environment are to be changed to 10 CFR Part 20, Appendix B, Table 2, Column 1.
4. References to 10 CFR, Parts 20.303 and 20.306 for sink and drain disposals are to be changed to 10 CFR 20.2003 and 10 CFR 20.2005 respectively.

The following appendices contained in the original license application require amending as the result of the above amendment request. They are:

Appendix I, Training and Experience of Individuals Responsible for the Use of Radioactive Materials

Delete: David Sanborn, Meiqing Lu, Ray Boutin, Kyonggeun Yoon, and Jean-Claude Dehmel

Add: Linda Snyder, Ph.D., authorized user who will be replacing Leslie Coney, Ph.D., as Radiation Safety Officer. Dr. Coney will continue as an authorized user and back-up RSO.

Richard Ciccarelli, Terry Higgins, Daniel McCallus, Malcolm Montgomery, Catherine Pachuk, C. Satishchandran, Khushroo Shroff, Kathleen Herold, Donald Sims and Felicia Watson as authorized users and/or direct supervisors of users.

George W. Moncrief of George Moncrief and Associates who will be replacing Jean-Claude Dehmel as radiation safety program consultant.

Training and Experience records are attached.

Name: LinderhyderDate: 6.5.86

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	U of PA, Princeton University, Sterling Winthrop Inc Apollon, Inc	2 hrs 4 hrs 10 hrs 1 hr	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	Same	same	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Same	same	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.	Same	same	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	250 μCi	U. of PA	3 yrs	DNA labelling
^{32}P	500 μCi	U. of PA, Princeton University, Sterling Winthrop, Apollon	14 yrs	DNA, RNA labelling
^{35}S	250 μCi	Princeton University, Apollon U of PA	8 yrs 14 yrs	cell labelling, DNA labelling

Name: C. S. AndersonDate: 6/7/96

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Memorial Univ of Newfoundland Canada	2d	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No
	Virginia Polytech Blacksburg Va	2d	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	Same as above	days → weeks	Yes No y	Yes No ✓
			y	✓
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Same place as above.	Part of the grad school progr. Part of the course prior to use of rad det	Yes No y	Yes No y
d. Biological effects of radiation.	MUN, Canada VPI, Blacksburg	2d 2d	Yes No	Yes No y ✓ y ✓

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	2 mCi	MUN, Canada and Fox Chase Cancer Ctr (FCCC)	1981-1985 MUN	Enzymology
^{14}C	100s mCi	MUN, Canada and FCCC	FCCC 1986-1993	in vivo labelling Enzymology
^{32}P	100s mCi	MUN, Canada and FCCC	1981-1993	in vivo labelling enzymology, Southern etc.
^{125}I	<1 mCi	MUN, Canada	1981-1985	Enzymology
^{54}Mn	<20 mCi	FCCC, PA.	1992 (1 yr)	Enzymology
^{35}S	100s mCi	MUN, Canada & FCCC, PA.		Sequencing, Enzymology

Name: Richard CiccarelliDate: June 7, 1996

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	1) Eastman Kodak Co Rochester, NY 2) Sterling Winthrop Rensselaer, NY	annual courses in the period 1985-1994	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.			<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.			<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.			<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	1 mCi	1) Eastman Kodak Co 2) Sterling Winthrop 3) MIT 4) Dartmouth	1979-1994	nucleic acid and protein labeling both
^{14}C	1 mCi			in cell culture and in vitro - also DNA
^{35}S	1 mCi			sequence analysis
^{32}P	500 μCi			

Name: KHUSHOO E. SHROFF.Date: 4th JUNE 1996.

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	1. UNIV. OF PENNSYLVANIA. 2. APOLLON INC.	→ 1/2 DAY. → 2 HRS.	Yes No	(Yes) No (YES)
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	RUTGERS UNIVERSITY	2 DAYS.	Yes No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	UNIVERSITY OF PENNSYLVANIA	-	(Yes) No	Yes No
d. Biological effects of radiation.	UNIVERSITY OF PENNSYLVANIA.		Yes No	(Yes) No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	average / 600 μCi	UNIV. OF PENNSYLVANIA	6 YEARS.	Biological Assays
^{51}Cr	100 μCi	UNIV. OF PENNSYLVANIA	6 YEARS	Biological Assays.
I^{125}	500 μCi	UNIV. OF PENNSYLVANIA.	6 YEARS.	Biological Assays.

Name: Catherine J. PachukDate: June 1, 1996

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Marywood College Scranton, PA U. of Penn. Smithline Centow Apollon	1 semester Formal Course in Nuclear Science + lab + Training Simulations	<u>Yes</u> No	<u>Yes</u> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.			<u>Yes</u> No	<u>Yes</u> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.			<u>Yes</u> No	<u>Yes</u> No
d. Biological effects of radiation.			<u>Yes</u> No	<u>Yes</u> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^{32}P	10 mCi/mx experiment	U. of Penn. for Smithline, Centow, Apollon	14 yrs	In vivo labelling of cellular RNA, in vitro labelling of proteins, run as transcriptionase
^{35}S	1.5 mCi	U. of Penn. Apollon, Centow, Smithline	14 yrs	In vivo labelling of proteins, DNA sequencing
^3H	100 mCi	Centow	1 yr	In vivo labelling of cellular DNA

Name: Dan McCallusDate: 6/5/86

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Agollon	1 hr.	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes <input checked="" type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	Agollon	1 hr	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes <input checked="" type="radio"/> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	West Hazelton High School	3 years	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.	Agollon	1 hr	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes <input checked="" type="radio"/> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^{35}S	5 mCi	U. Penn Agollon	3 years	metabolic labelling of proteins

Name: Terry Higgins

Date: 7/31/86

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Sterling Winthrop (+ other places)	2 days at start yearly refresher	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	"	"	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	"	"	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.	"	"	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^{125}I	5 mCi	Australian National University Univ. of Pennsylvania	4 yrs 6 yrs	cell + protein labelling
^{35}S	10 mCi	U. of Penn.	6 yrs	"
^3H ^{14}C	10 mCi	Harvard Univ. Univ. of Calif. - Davis Australian Natl. Univ. U. Penn. Sterling Winthrop	4 yrs 2 yrs 4 yrs 6 yrs 7 yrs	metabolic labelling cell proliferation
^{51}Cr	5 mCi	A. N. U. U. Penn.	4 yrs 2 yrs	cell labelling

Name: Malcolm Montgomery

Date: 5-31-96

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Duke U. Med. Center	2 days	Yes <u>No</u>	<u>Yes</u> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	"	"	Yes <u>No</u>	<u>Yes</u> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	"	"	Yes <u>No</u>	<u>Yes</u> No
d. Biological effects of radiation.	"	"	Yes <u>No</u>	<u>Yes</u> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	250 μCi	Duke U. Medical Center	2 yrs	Sipped Sample Expts
^{51}Cr	"	"	"	"
^{32}P	"	"	"	"

Name: Don SimsDate: 5/31/96

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Apollo	2 yrs	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	Apollo	2 yrs	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Apollo	2 yrs	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.	Apollo	2 yrs	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	50 μC	Rice University	2 yr	labelling, Assay
^{14}C	50 μC	Rice University	2 yr	labelling, Assay

Name: FELICIA WATSONDate: 6/3/96

TRAINING

TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Holy Family College Wistar Institute	3 Mo ~3 year	Yes <input checked="" type="radio"/> No <input type="radio"/> <input checked="" type="radio"/> Yes	<input checked="" type="radio"/> Yes <input type="radio"/> No Yes <input checked="" type="radio"/> No
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	SAME AS ABOVE + SBR&D	1 DAY every Year for 6 YEARS	Yes No <input checked="" type="radio"/> Yes	Yes No <input checked="" type="radio"/> Yes
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Holy Family College	3 Mo.	Yes No	<input checked="" type="radio"/> Yes <input type="radio"/> No
d. Biological effects of radiation.	All of The Above		Yes No	Yes No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^3H	50 μCi	Wistar Institute	~4 Mo.	IN-situ Hybridization
^{32}P	Varied 150 μCi - 900 μCi	Wistar S-B Apollon	ON AND OFF for the PAST 11 years	Blots/Sequencing
^{35}S	50 - 400 μCi	Wistar S-B Apollon	" "	Sequencing/ RIPS
^{125}I	5 - 100 μCi	S-B	6 years	Westerns [No Iodinations!]

Name: L. Conny

Date: _____

TRAINING

TYPE OF TRAINING	WHERE TRAINEED	DURATION OF TRAINING	ON-THE-JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
a. Principles and practices of radiation protection	Univ. of Va Yale Univ. Centocor Apollon Harvard Pub. School of Health → 1 wk	3h 2h 1h 1h	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> Yes No All over formal course.
b. Radioactivity measurements, standardization and monitoring techniques, instruments.	SAME as above		Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity.			Yes No	Yes No
d. Biological effects of radiation.			Yes No	Yes No

EXPERIENCE

(Actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience was Gained	Duration of Experience	Type of Use
^{32}P	1mCi	Univ. of Va Yale Univ. Centocor Apollon	16 y.	Molecular Biological
^{125}I	5mCi	Centocor	3 y	Biochemical
^3H	1mCi	Centocor.	1 y	Tissue culture
^{35}S	1mCi	Centocor	2 y	Molecular Biological

GEORGE W. MONCRIEF
1542 Pennsbury Drive
West Chester, PA 19382
(610) 436-8706(Phone)

EHS & RADIOLOGICAL SAFETY CONSULTANT

PROFESSIONAL AFFILIATIONS

American Institute of Chemical Engineers
American Biological Safety Association
American Chemical Society
National Safety Council, Research, Development & Emerging
Technologies Section. Executive committee member. Currently
General Chairperson Elect in progression to be General Chairperson
in 1997.

QUALIFICATIONS

Thirty years EHS experience including nine years as radiation safety officer for a pharmaceutical research laboratory and 5 years consulting experience in diverse areas such as:

- o RCRA hazardous chemical waste, Pennsylvania residual waste, infectious medical/biowaste, and NRC low level radioactive waste management.
- o Pennsylvania Source Reduction Strategy (waste minimization) program for hazardous and residual waste for research and development facility.
- o RCRA hazardous waste general awareness employee training.
- o Spill Prevention Control and Countermeasure (SPCC) plans.
- o Pennsylvania and Delaware air permit exemption applications for laboratory small emission sources.
- o Industrial waste water permit applications for research and development facilities, including radioisotope sewer discharge.
- o Pennsylvania General Stormwater Permit.
- o Environmental procedures manual for research and development generators of hazardous chemical, biological and radiological waste.
- o NRC license amendments, including conversion from old to new 10 CFR 20 requirements.

EMPLOYMENT PRIOR
TO CONSULTING
CAREER

DUPONT COMPANY, INC

Safety, Occupational Health & Environmental Supervisor
Glenolden Laboratory, Glenolden, PA (1981 -1990)

Managed a total safety, health and environmental affairs program involving chemical, biological and radioactive materials. Managed hazardous chemical, biological and radioactive waste, asbestos abatement, soil and groundwater contamination studies. Prepared sewer discharge permits and air emission permits. Set up a low level radioactive waste management facility including a decay in storage, interim storage and volume reduction facilities.

Safety Engineer

Jackson Laboratory, Deepwater, NJ (1967-1981)

Responsible for all phases of organic chemistry research laboratory and pilot plant safety including process hazards reviews. Hazardous chemicals included carcinogens and unstable nitro compounds.

Survey Engineer (1965-1967)

Occupational Health & Fire Protection Division, Wilmington, DE.

Conducted safety and fire protection management program audits of Dupont sites throughout U.S.

FACTORY MUTUAL ENGINEERING DIVISION,
Philadelphia District

Loss Prevention Engineer, 1960 - 1965.

Conducted chemical plant fire protection audits and tested fire protection systems.

EDUCATION

Bachelor of Science Degree in Chemical Engineering from
Northeastern University, Boston, Massachusetts. 1960

Numerous Dupont internal and external training courses including 40-hour RSO training and biennial update seminars. 1981 - 1994

Professional Engineer Review Course, Drexel University, Phila., Pa. 1992.

Certified 40-hr OSHA 1910.120 hazardous waste operations trainer.

Appendix II Information used for Training Individuals Working In or Frequenting Controlled or Restricted Areas "

The following definitions are to be added to the training information given to workers frequenting Controlled or Restricted Areas:

ALARA:	Acronym for "as low as reasonably achievable " which means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.
ANNUAL LIMIT on INTAKE	The amount of radioactive material taken into the body of an adult worker adult worker (reference man) by inhalation or ingestion in a year that would result in a committed effective dose equivalent of 5 rems or a committed dose equivalent of 50 rems to any individual organ or tissue. UNIT = uCi.
BIOASSAY	The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement or by analysis and evaluation of materials excreted or removed from the human body.
COMMITTED DOSE EQUIVALENT	The dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake. UNIT = rem.
COMMITTED EFFECTIVE DOSE	The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues. UNIT = rem.
CONTROLLED AREA	An area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.
DECLARED PREGNANT WOMAN	A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.
DEEP-DOSE EQUIVALENT	The external whole-body dose equivalent at a tissue depth of 1 cm. UNIT = rem.

DERIVED AIR CONCENTRA- TION (DAC)	The product of the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2000 hours under conditions of light work results in an intake of one Annual Limit on Intake (ALI). UNIT = uCi/ml
EFFECTIVE DOSE EQUIVALENT	The sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. UNIT = rem.
EYE DOSE EQUIVALENT	The external exposure to the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter.
HIGH RADIATION AREA	An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem in 1 hour at 30 cm from the radiation source or from any surface that the radiation penetrates.
RADIATION AREA	An area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem in 1 hour at 30 cm from the radiation source or from any surface that the radiation penetrates.
RESTRICTED AREA	An area, access to which is limited by the licensee for the purpose of protecting individuals from undue risk.
TOTAL EFFECTIVE DOSE	The sum of the deep dose equivalent (for external exposure) and the committed effective dose equivalent (for internal exposures)

The remainder of Appendix II is unchanged.



Apollon

August 21, 1996

License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

To Whom It May Concern:

Apollon, Inc. applied for an amendment to material license number 37-28782-01 in July, 1996. We enclosed a check for \$590, which was inadequate to cover the cost of the fee, \$610. I have enclosed a check for the remaining \$20, and attached a copy of the paperwork I received regarding this matter.

If you have any questions, please call me at (610) 647-9452. Thank you.

Sincerely,

Linda A. Snyder

1996 AUG 23 PM 4:11

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

APOLLON, INC.
ATTN: LESLIE CONEY, PH.D.
GREAT VALLEY CORPORATE CENTER
ONE GREAT VALLEY PARKWAY
MALVERN, PA 19355-1307

TYPE OF ACTION

- ☐ NEW LICENSE
☐ RENEWAL OF LICENSE
☒ AMENDMENT TO LICENSE

REQUESTED DATE

7-19-96

LICENSE NUMBER

37-28782-01

CONTROL NUMBER

123493

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3M	\$	\$	\$ 610.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	610.00
PAYMENT RECEIVED	\$	590.00
AMOUNT DUE	\$	20.00

☒ Your request was received without the prescribed application fee.

☒ We received your Check No. 11517 in the amount of \$ 590.00. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- ☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

- ☐ Enclosed is Check No. _____ which was returned to us by the bank for:
- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- ☐ License No. _____, Amendment No. _____, issued on _____, was issued without the required fee being collected. The fee required is noted in Section I of this form.
- ☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

SIGNATURE -- LICENSE FEE ANALYST

BRENDA BROWN

LFDCB

BB *BB*
8/7/96

LFDCB

Distribution:

MAF Correspondence FY

LFDCB Chief

Invoice File w/encl

LFDCB Analyst

LFDCB R/F

DAF R/T

DATE

8-7-96

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 20030331
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: APOLLON, INC.
RECEIVED DATE: 960725
DOCKET NO: 3032892
CONTROL NO.: 123493
LICENSE NO.: 37-28782-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$590.00
CHECK NO.: 11577

3. COMMENTS

SIGNED
DATE

M. A. Perkins
7/25/96

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

1. FEE CATEGORY AND AMOUNT: 3M \$60

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

SC
8/30/96

Log	<u>Aug 5</u>
Remitter	
Check No.	<u>11577 / 11868</u>
Amount	<u>\$590.00 / \$20</u>
Fee Category	<u>3M</u>
Type of Fee	<u>Amend</u>
Date Check Rec'd	<u>8/30/96</u>
Date Completed	
By	<u>SC</u>