

## MATERIALS LICENSE

Amendment No. 19

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.

301826

Licensee		In accordance with letter dated August 29, 1996	
1. Pharmacia Biotech, Inc. Molecular Biology Reagents Division		3. License Number 48-14075-01 is amended in its entirety to read as follows:	
2. 2202 N. Bartlett Avenue Milwaukee, WI 53202		4. Expiration Date May 31, 2003	
		5. Docket or Reference No. 030-07706	
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. 10 millicuries	
B. Carbon-14	B. Any	B. 20 millicuries	
C. Phosphorus-32	C. Any	C. 50 millicuries	
D. Phosphorus-33	D. Any	D. 10 millicuries	
E. Sulfur-35	E. Any	E. 25 millicuries	
F. Iodine-125	F. Any	F. 5 millicuries	

## 9. Authorized Use:

A. through F. For in-vitro laboratory research and development as specified in 10 CFR 30.4.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2202 N. Bartlett Avenue, Milwaukee, Wisconsin.
11. The Radiation Safety Officer for this license is Edward J. Adolphson.

260022

9610280006 961016  
PDR ADOCK 03007706  
C PDR

COPY

01  
2 ml  
30  
SD

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

48-14075-01

Docket or Reference Number

030-07706

Amendment No. 19

12. Licensed material listed in Item 6. above is authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. Jeffrey Trost, Ph.D., ALL.
  - B. Gregory J. Johnson, ALL.
  - C. Carl E. Wolff, Items 6.A., 6.B., 6.C., 6.D., and 6.E.
  - D. Peter A. Bell, Ph.D., ALL.
  - E. Edward J. Adolphson, ALL.
  - F. Christopher Lively, Ph.D., ALL.
  - G. Karen Foster, B.S., M.S., ALL.
  - H. Phillip P. Franciskovich, Ph.D., ALL.
  - I. William Riedl, Ph.D., Items 6.A., 6.B., 6.C., 6.D. and 6.E.
13. Licensed material shall not be used in or on human beings.
14. This license does not authorize commercial distribution of licensed material.
15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
16. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
  - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter 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.

COPY

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- C. A record of each disposal permitted under this License Condition shall be retained for 3 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.
17. Survey instrumentation shall be calibrated at intervals not to exceed 12 months, by a firm licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 8, 1993; and
- B. Letters dated October 19, 1993 and March 14, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 16, 1996

By

Robert R. Matson  
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 03620  
Status Code: 0  
Fee Category: 3M  
Exp. Date: 20030531  
Fee Comments:  
Decom Fin Assur Req'd: N

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: PHARMACIA BIOTECH INCORPORATED  
Received Date: 960913  
Docket No: 3007706  
Control No.: 301826  
License No.: 48-14075-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 610  
Check No.: 2253230

3. COMMENTS

Signed  
Date

*S. Hersey*  
*9-16-96*

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

1. Fee Category and Amount: 3M \$610

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

Amendment  
Renewal  
License

3. OTHER

Signed  
Date

*SC*  
*9/24/96*

1996 SEP 20 AM 11:56

SEP 30 1996

Log	<i>SEP 7 III</i>
Remitter	
Check No.	<i>53230</i>
Amount	<i>\$610</i>
Fee Category	<i>3M</i>
Type of Fee	<i>Amnd</i>
Date Check Rec'd	<i>9/20/96</i>
Date Completed	<i>9/24/96</i>
By:	<i>SC</i>

August 29, 1996

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
801 Warrenville Rd.  
Lisle, IL. 60532-4352

Re: NRC License #48-14075-01

Dear Sir or Madam:

This letter is to amend our current NRC License. These changes will affect items 7 & 9 of the license application dated 11/8/93 and license amendment #18 dated June 9, 1995.

Please delete the following Group I Users:

C. James Jolly  
E. Howard Coyer  
G. Ponnusamy Ramanujam  
H. Brent Burdick

Please add Denise Girschner as a Group I User on the NRC License and approve her for all isotopes under item 5. Enclosed is Ms. Girschner's Curriculum Vitae. She will be responsible for the direct supervision of Group II users in Lab 1242, ( Q.C. Lab).

I have performed the formal training in a) principles and practices in radiation protection, b) radiation measurements and monitoring techniques c) mathematics and calculations basic to the use of and measurements of radioactivity, and d) biological effects of radiation stochastic and non-stochastic.

Ms. Girschner will obtain further continuing education in radiation safety at the next course offering at Northwestern University ( Continuing Professional Development).

Under item #9 of the license application we wish to close-out Lab 1211 as a fully restricted laboratory in the use of radiochemicals. Lab 1211 will no longer be used for radiochemical experiments, please remove it from the license. This lab was heavily utilized for <sup>32</sup>P DNA sequencing back in the late 80's and early 90's. Today most DNA sequencing is done with non-isotopic automated laser sequencers. Please review the meter surveys and wipe test enclosed. All equipment labeled with a radioactive sticker shall either be decontaminated to background or removed from the lab and put into another

**RECEIVED**

**SEP 13 1996**

**REGION III**

**SEP 13 1996**

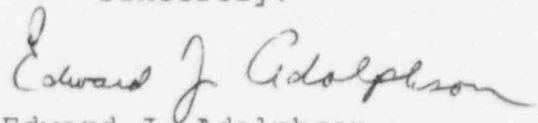
*pm. 9-10-96*

*301826*

radiochemical laboratory. During the interim between receiving and approving this amendment; no radioactive material will be allowed in or used in Room 1211.

If you have any questions or concerns about the above three actions, please contact myself at 414-227-3732. Thank you.

Sincerely:

A handwritten signature in cursive script, reading "Edward J. Adolphson". The signature is written in dark ink and is positioned above the printed name.

Edward J. Adolphson  
Regulatory Compliance Officer



## DENISE M. GIRSCHNER

3545 S. McIntosh Lane  
New Berlin, WI 53151  
(414) 938-0554

### PROFESSIONAL OBJECTIVE:

A management opportunity in a medical manufacturing environment allowing me to expand my leadership, management, and technical skills. A position that will lead to the development of a long term, mutually beneficial relationship with a prosperous company, with the opportunity for future advancement.

### CAREER SKILLS SUMMARY:

- Write, train and review Standard Operating Procedures
- Design and implementation of quality control systems
- Write and review study protocols, project instructions, and study reports
- Extensive planning, scheduling, prioritizing, and organizational skills
- New method evaluation, development, pricing, and implementation
- Interpretation and application of GLP/GMP
- Interpretation and application of EPA/FDA/USDA Guidelines & Regulations
- Review and verification of data and quality records
- Supervisory and training skills
- Client consultation
- Development of key performance statistics, charts, agendas, data collection
- Team Development
- Fishbone Diagrams, and other problem solving tools
- Visual Inventory Management Systems, Workplace Organization and Process Optimization
- Conflict Resolution and Customer Complaints

### ACCOMPLISHMENTS:

- Implemented new methodologies compliant to regulatory guidelines.
- Evaluated the feasibility and profitability of new methods
- Acquired and scheduled studies, and any related equipment, materials, personnel, and facilities.
- Coordinated all operational activities for a busy testing laboratory.
- Initiated new and revised quality control records needed to substantiate study validity.
- Created new data collection system that improved compliance, yet reduced paperwork by more than 40%.
- Responded to regulatory auditors questions and assisted in responding to regulatory audit reports.
- Increased laboratory capacity/business three fold, through productivity gains and client referrals.
- Developed and implemented protocols as a project monitor and study director.
- Implemented many permanent work teams in various manufacturing facilities including pharmaceutical/medical, packaging, plastic molding, and human service environments.
- Effectively trained of groups and individuals at all levels in organizations on various technical methods, management, and quality improvement tools.
- Served on a team that developed a company wide new hire training manual.

## EMPLOYMENT HISTORY:

### Smith & Nephew Rolyan Inc.

Germantown, WI Present

**Assistant Manager of Quality Assurance** Responsible for supervising all personnel and functions of the Quality Assurance Department including incoming inspection, laboratory testing, and customer complaints for an ISO 9000 registered medical rehabilitation products manufacturing facility. Serve on product development teams and work closely with production managers and engineers in troubleshooting defects and process validation. Conduct company wide internal audits and training for compliance to ISO requirements.

### Systems Management Group

Kalamazoo, MI 1995-1996

**Operations Specialist** Responsible for the implementation of permanent work teams in organizations. Development of key performance statistics, charts, agendas, data collection sheets, and team statistics sheets. Conduct training and coaching of groups and individuals at all levels in the organization on Team Development, Ideas & Suggestions, Workplace Organization, Standard Operating Procedures, Fishbone Diagrams, Visual Inventory Management Systems, Process Optimization, ISO 9000, GLP/GMP, and others.

### Hill Top Biolabs, Inc.

Miamiville, OH 1990-1995

**Section Head, Microbiology Division** Responsible for the coordination of operational activities for the Disinfectant Testing Section. Acquire and Schedule studies, and any related equipment, materials, personnel, and facilities. Active in new method evaluation, development, pricing, and implementation. Generation of necessary Standard Operating Procedures. Interpret and Apply GLP/GMP and EPA/FDA/USDA Regulations. Consult with clients and recommend appropriate test procedures accompanied by price quotations. Review and verify data and reports generated by the section. Develop and expand technical expertise of Research Associates and Technicians under supervision.

**Research Associate, Microbiology Division** Provided technical expertise to the division by ensuring that studies were being conducted according to proper procedures, including monitoring the quality control records necessary to substantiate study validity. Trained Research Associates and Technicians. Acted in test development role by evaluating the feasibility of new methods for the division. Wrote project instructions and reports upon study completion.

### Becton Dickinson Polymer Research

Miamisburg, OH 1989-1990

**Research Technician, Product Development and Applications Group** Designed, developed, performed and recorded research experiments with intravenous indwelling catheters. Also wrote Standard Operating Procedures and project reports using word processing and graphics software.

## EDUCATION:

### **BACHELOR OF SCIENCE: Medical Technology with a Business Minor Michigan Technological University - 1989**

Professional Courses Include: Biochemistry, Urology and Body Fluid Analysis, Microbiology, Medical Bacteriology, Immunology and Serology, Clinical Chemistry, Clinical Laboratory Quality Control and Management, Clinical Hematology, Hemostasis, Immunohematology, Mycology, Medical Parasitology, Laboratory Instrumentation, Principals of Marketing, Economics of Health Care, Industrial Marketing and Procurement, Hospital Administration, Labor and Industrial Relations, Personnel Management, Leadership of Groups.

## ADDITIONAL TRAINING:

Hill Top Companies "Pre-supervisory Management Development Program".  
Xavier University "Development of the First Line Supervisor".  
Systems Management Group "Shop Floor Management".

## PROFESSIONAL INVOLVEMENT:

- Microbiology Representative of the Hill Top Companies - Associates Relations Committee
- Microbiology Representative of Hill Top Biolabs -Task Force, and Training Committee
- Representative of Hill Top Biolabs - CSMA, CAQ Lab Accreditation Task Force
- Member of the American Society of Quality Control

## REFERENCES:

Professional references will be furnished upon Request



\* light switch missing plate

Meter  
0.05 mR/h

(1) Door

1. Minir Monitor 5.10 S. # 20960  
calibration 12/15/95

2. Bindex - 14C Serial # 116112  
calibration date 6/19/96

- |     |                                    |           |
|-----|------------------------------------|-----------|
| 2.  | Floor of S. side                   | 0.05 mR/h |
| 3.  | " N. side                          | 0.05 mR/h |
| 4.  | S. Bench                           | 0.05 mR/h |
| 5.  | N. Bench                           | 0.05 mR/h |
| 6.  | floor where rad trash kept.        | 0.05 mR/h |
| 7.  | drawer with rad stickers           | 0.05 mR/h |
| 8.  | " " "                              | 0.05 mR/h |
| 9.  | rad trash <sup>25</sup> S-dry wash | 0.05 mR/h |
| 10. | Broken glass containers            | 0.05 mR/h |
| 11. | Telephone - N.W. side              | 0.05 mR/h |
| 12. | Refrigerator                       | 0.05 mR/h |
| 13. | Sink N end + drain                 | 0.05 mR/h |
| 14. | " S. end                           | 0.05 mR/h |
| 15. | Bio fuge - N. Bench                | 0.05 mR/h |
| 16. | Film cassette                      | 0.05 mR/h |
| 17. | film cassette                      | 0.05 mR/h |
| 18. | " "                                | 0.05 mR/h |
| 19. | " "                                | 0.05 mR/h |
| 20. | N.E. bench                         | 0.05 mR/h |
| 21. | H <sub>2</sub> O Bath              | 0.05 mR/h |
| 22. | beta box                           | 0.05 mR/h |
| 23. |                                    |           |
| 24. | beta blocks                        | 0.05 mR/h |
| 25. |                                    |           |
| 26. |                                    |           |
| 27. | test tube                          | 0.05 mR/h |
| 28. | beta holder                        |           |

Meter Surveys of lab 1211 performed

9/3/96  
E.A.

22

Pipettes

41

42 Eppendorf centrifuge

43 vortex

44 H<sub>2</sub>O bath

45 ap Waste container + lid

46 Beta shield

47 ice bucket

Survey

&lt;0.05 mPh

&lt;0.05

&lt;0.05

&lt;0.05

&lt;0.05

&lt;0.05

&lt;0.05

Motor - PUG 1

all areas at BKGD,  
refrigerator emptied.

- | #  | Wipe Test Location               |
|----|----------------------------------|
| 1  | Outside Door                     |
| 2  | Top of fringe                    |
| 3. | sides of fringe                  |
| 4  | inside door of fringe            |
| 5. | Bottom shelf L side              |
| 6  | " " R. side                      |
| 7. | Top shelf L. side                |
| 8. | <del>Top</del> Top shelf R. side |

Empty refrigerator in Lab 1211  
can be removed for repair

Ed Adolphson R50  
EX 3732

Motor Survey + Wipe Test  
of Refrigerator located in.  
Lab 1211.

Ed Adolphson  
8-29-96.

(All areas surveyed &  
wipe - tested found  
to be at Background)

Results  
BKGD  
BKGD  
BKGD  
BKGD  
BKGD  
BKGD  
BKGD  
BKGD

S#	TIME	CPMA	CPMB	DFM1	DFM2	tSIE	SIS	FLAG
2	10.00	110105.	119092.	196305.	3173.67	902.	19.93	L
3	10.00	94034.1	12313.9	192025.	4018.16	654.	16.100	L
4	10.00	82701.1	11715.6	191832.	3891.31	527.	14.080	L
5	10.00	69475.4	10425.6	190790.	3336.55	408.	12.200	L
6	10.00	49772.6	8241.20	189717.	2678.77	280.	10.090	L
7	10.00	41331.6	7984.80	187566.	2848.04	236.	9.370	L
8	10.00	31877.4	7112.20	188457.	2455.87	193.	8.600	L
9	10.00	25499.8	5953.90	187141.	2122.64	163.	8.080	L
10	10.00	19734.3	4827.10	183569.	1837.69	136.	7.580	L
11	10.00	15251.2	3973.10	183217.	1539.44	114.	7.220	EL
12	10.00	14845.0	111242.	0.00	131780.	916.	157.04	H
13	10.00	14088.2	110388.	0.00	132658.	660.	114.93	H
14	10.00	13547.3	109778.	0.00	132699.	533.	95.120	H
15	10.00	13514.3	107827.	0.00	133322.	406.	73.450	H
16	10.00	13118.9	105029.	0.00	133511.	282.	53.100	H
17	10.00	12471.7	102637.	0.00	133613.	227.	43.550	H
18	10.00	11990.2	99933.1	0.00	134214.	186.	36.530	H
19	10.00	12004.6	96331.1	0.00	134003.	156.	31.510	H
20	10.00	12406.7	90809.9	0.00	134510.	128.	26.280	H
21	10.00	12418.8	85691.7	0.00	135029.	109.	22.940	EH
22	10.00	0.00	1.20	0.00	1.49	450.	70.770	BRAD
23	10.00	0.00	1.60	0.00	1.99	439.	83.050	outside door
24	10.00	0.00	1.80	0.00	2.26	404.	156.48	floor south side
25	10.00	0.00	1.50	0.00	1.88	412.	132.44	South Bench.
26	10.00	0.00	2.80	0.00	3.52	398.	143.11	North Bench
27	10.00	0.00	2.50	0.00	3.12	425.	26.530	floor north side
28	10.00	0.00	1.90	0.00	2.39	382.	116.56	floor where rad trash kept.
29	10.00	0.00	2.50	0.00	3.13	420.	50.580	drawer with radiation sticker
30	10.00	0.00	1.00	0.00	1.24	443.	102.48	drawer with radiation sticker
31	10.00	0.00	2.80	0.00	3.51	407.	111.92	<sup>25</sup> S dry waste container.
32	10.00	0.00	1.30	0.00	1.62	433.	60.450	Broken glass container.
33	10.00	0.00	1.60	0.00	1.99	447.	73.570	telephone Northwest side
34	10.00	0.00	1.00	0.00	1.25	432.	124.35	Refrigerator - (see earlier wipe +
35	10.00	0.00	1.60	0.00	2.03	349.	186.71	sink N. end + drain.
36	10.00	0.00	1.30	0.00	1.64	364.	101.55	sink south end
37	10.00	0.00	1.90	0.00	3.44	80.2	107.20	Biöfuge North bench
38	10.00	0.00	3.30	0.00	4.13	411.	49.600	film cassette
39	10.00	0.00	2.90	0.00	3.64	396.	104.46	film cassette
40	10.00	0.00	1.80	0.00	2.25	429.	60.180	film cassette
41	10.00	0.00	1.60	0.00	1.99	442.	68.420	film cassette
42	10.00	0.00	1.50	0.00	1.88	417.	62.380	North east bench
43	10.00	0.00	2.60	0.00	3.26	412.	125.03	H <sub>2</sub> O bath
44	10.00	0.00	2.60	0.00	3.24	439.	0.000	beta box
45	10.00	0.00	2.50	0.00	3.12	423.	93.370	beta block
46	10.00	0.00	0.20	0.00	0.25	433.	77.330	"
47	10.00	0.00	1.70	0.00	2.12	428.	33.220	"
48	10.00	0.00	1.90	0.00	2.37	437.	95.810	beta block.
49	10.00	0.00	2.50	0.00	3.12	422.	72.680	beta box
50	10.00	0.00	3.50	0.00	4.40	389.	154.68	test tube holder.
51	10.00	0.00	1.80	0.00	2.24	443.	88.700	
52	10.00	0.00	1.90	0.00	2.37	434.	111.11	
53	10.00	0.00	1.00	0.00	1.24	441.	57.700	
54	10.00	0.00	3.20	0.00	3.99	433.	65.180	
55	10.00	0.00	2.40	0.00	2.99	439.	37.450	
56	10.00	0.00	1.10	0.00	1.37	442.	106.67	
57	10.00	0.00	0.70	0.00	0.87	445.	85.680	

<sup>3</sup>H + <sup>14</sup>C

Quenched

Std.

<sup>3</sup>H efficiency - 65%

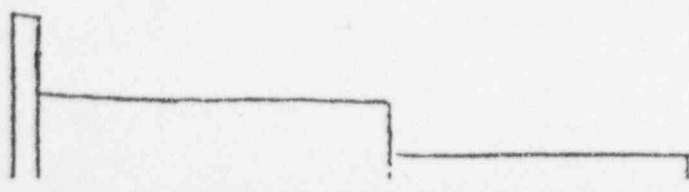
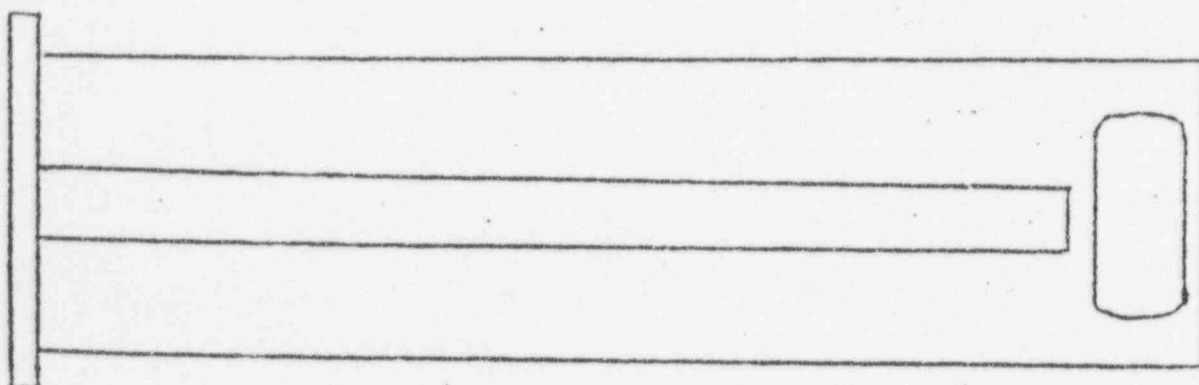
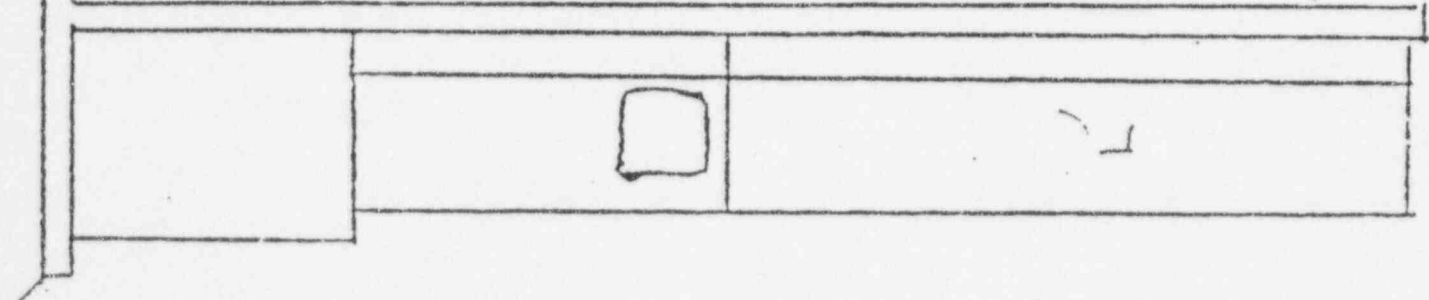
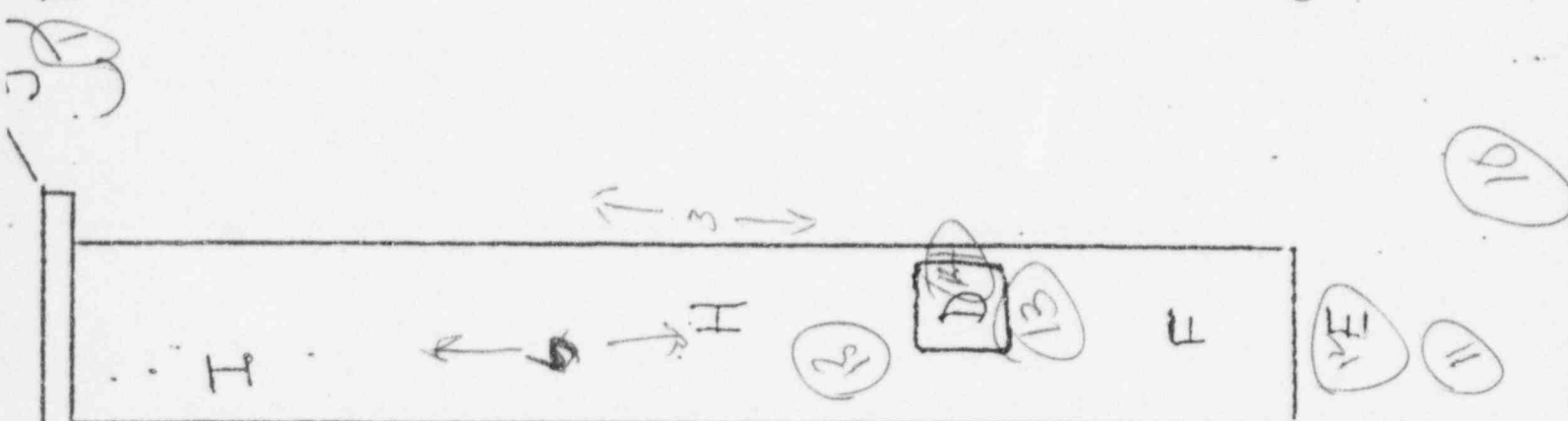
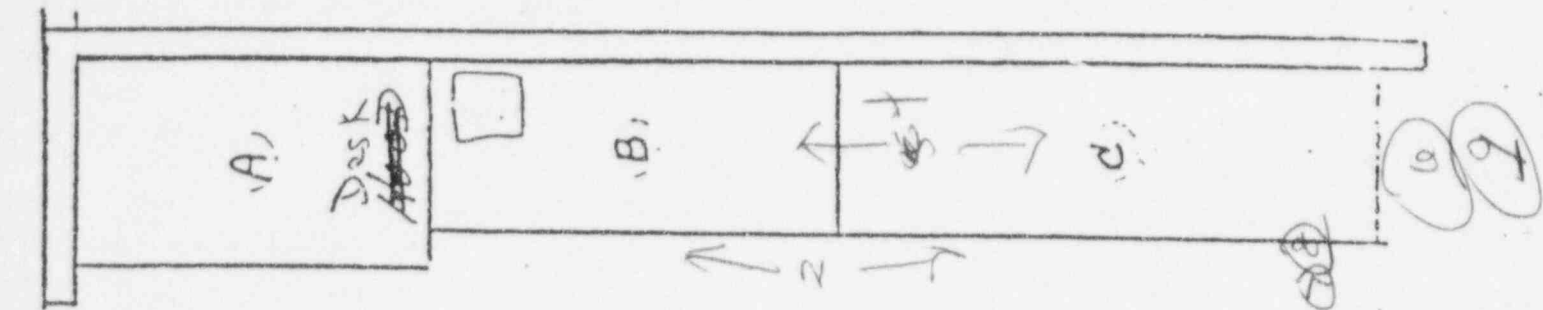
<sup>14</sup>C efficiency - 85%

pipettes.

S#	TIME	CPMA	CPMB	DPM1	DPM2	tS1E	S1S FLAG
58	10.00	0.00	1.70	0.00	2.12	442.	70.680
59	10.00	0.00	1.60	0.00	1.99	443.	32.650
60	10.00	0.00	0.20	0.00	0.25	437.	97.160
61	10.00	0.00	3.90	0.00	4.85	444.	0.000
62	10.00	0.00	2.10	0.00	2.61	445.	94.510
63	10.00	0.00	2.70	0.00	3.36	445.	661.26
64	10.00	0.00	1.70	0.00	2.14	382.	64.600 - eppendorf centrifuge
65	10.00	0.00	0.50	0.00	0.62	427.	91.870 - vortex
66	10.00	0.00	3.20	0.00	4.03	380.	89.980 - H <sub>2</sub> O bath
67	10.00	0.00	0.00	0.00	0.00	414.	90.130 - P waste container + lid
68	10.00	0.00	1.60	0.00	2.02	384.	140.28 - beta shield
69	10.00	0.00	1.60	0.00	2.00	412.	90.170 - ice bucket

\* all areas surveyed with Ludlum G.M. survey meter on 0.1 scale  
 $\leq 0.05 \text{ mR/m}$ .

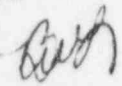
E.A.  
9-4-96.



Row data  
to close-out  
of 12/11



## MEMORANDUM

TO: E. Adolphson cc. P. Ehrenheim  
FROM: B. Leander   
DATE: Mon, Aug 26, 1996  
SUBJECT: Decommission room 1211

---

It has been decided we will decommission room 1211 for the use of radioactivity. Would you please begin the process and notify anyone that needs to be informed. Thank you.

OCT 17 1996

Edward J. Adolphson  
Regulatory Compliance Officer  
Pharmacia Biotech, Inc.  
Molecular Biology Reagents Division  
2202 N. Bartlett Avenue  
Milwaukee, WI 53202

Dear Mr. Adolphson:

Enclosed is Amendment No. 19 to your NRC Material License No. 48-14075-01 in accordance with your request.

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

Please note that the expiration date of your license has been changed to reflect the automatic five-year extension granted under a regulatory change.

We have not added Ms. Girschner as an authorized user at this time. As discussed in our telephone conversation on September 25, 1996, she needs to obtain actual handling experience with radionuclide before she can be permitted to work without supervision. When you submit the addition experience she has obtained, please state that it is additional information to Control No. 301826 and we will continue our review.

In addition, we have not delete Lab 1214 based on your letter dated September 30, 1996. Therefore, Lab 1214 is considered to be a restricted area for the purpose of radiation protection. When providing addition information about the Lab, please refer to Control No. 301826.

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

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

301826

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

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

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

E. Adolphson

-3-

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By  
Evelyn R. Matson  
Nuclear Materials Licensing Branch

License No.: 48-14075-01  
Docket No.: 030-07706

Enclosure: Amendment No. 19

DOCUMENT NAME: M:\03007706.CL6

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

OFFICE	DNMS/RIII <i>EM</i>	<input checked="" type="checkbox"/> N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	EMATSON:jaw								
DATE	10/1/96								

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Section  
801 Warrenville Rd.  
Lisle, IL. 60532-4352

Sept. 30, 1996

Re: License Amendment to NRC License # 48-14075-01  
Control # 301826

Dear Ms. Matson:

Enclosed is a Curriculum Vitae of Mr. C. Wolff, who we wish to make a Group I User for Radiochemicals, Lab 2314. Hopefully, you will find this complete and have him authorize to use:

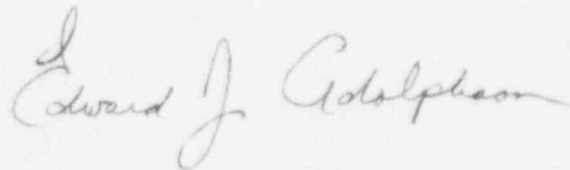
$^3\text{H}$ ,  $^{14}\text{C}$ ,  $^{32}\text{P}$ ,  $^{33}\text{P}$  and  $^{35}\text{S}$  radiochemicals.

Mr. Wolff has been employed with us for 5 years and has had experience with all aspects of the Radiation Safety Program.

As per your telephone message, there is no need to immediately release Lab 1214. It can wait until you can review both Group I applicants. As to Ms. Girschner, not having the Radiochemical experience, this is true, and I will leave it to your discretion. During the interim, we will have her record radiochemical procedures she has performed with amounts. Both Mr. Wolff and her will attend the radiation physics course offered by Northwestern University-Continuing Education; (Dr. Cember). From phone conversations, this may have to wait until Spring until it is offered again.

Thank you for waiting until this C.V. of Mr. Wolff's (for a Group I User) as to processing this License Amendment. As with most businesses, change is constantly occurring.

Sincerely,



Edward J. Adolphson  
Regulatory Compliance Officer

**RECEIVED**

**OCT 03 1996**

**REGION III**

**OCT 03 1996**

## CARL E. WOLFF

Pharmacia Biotech, Inc. - Milwaukee  
2202 N Bartlett Avenue  
Milwaukee, WI 53202  
Telephone: (414) 227-2358

### EXPERIENCE:

(9/16/96-Present)  
(1/95-9/96)  
(8/91-12/94)

Pharmacia Biotech, Inc.  
**Production Supervisor, Enzymes**  
**Senior Production Chemist**  
**Production Chemist**

Successfully produced products in all areas of the Enzyme Production group: Modifying Enzymes, Restriction Enzymes, Antibody-related products and Calibration Kits. Received cross-training and produced batches in the Amidite production group. Trained new associate and production chemists. Maintained accurate, up to date and precise production records. Maintained the accuracy of ISO 9001 Protocols and Standard Operating Procedures.

Served as the production department member of the launch teams for Taq DNA Polymerase and the RTG You-Prime 1st Strand Kit. Introduced improvements and refined processes, resulting in reduced costs, increased yields and better product consistency for some of our major products (e.g. Terminal Deoxynucleotidyl Transferase (TdT)). Co-recipient of merit award for work performed in the successful launch of Taq DNA Polymerase.

(6/86-8/91)

National Biomedical ESR Center, Medical College of Wisconsin  
**Senior Research Technician**

Designed and conducted experiments, resulting in 6 publications in professional journals and an oral presentation at the Biophysical Society National Meeting. Employed fluorescence spectroscopy, UV/Vis, CD, HPLC/FPLC, column chromatography, electrophoresis, transfer/blotting techniques, ELISA and analytical ultracentrifugation, in protein and peptide identification, purification and characterization. Developed/adapted computer programs for data analysis.

(1983-1986)

University of Wisconsin-Milwaukee, Dept. of Chemistry  
**Graduate Research Assistant**

Prepared and characterized various fluorescently labeled transfer-RNA's. Studied the effects of solution conditions on dynamic and structural properties of t-RNA. Supervised/guided undergraduate assistants in performing experiments.

(1981-1983)

University of Wisconsin-Milwaukee, Dept. of Chemistry  
**Graduate Teaching Assistant**

Taught lab discussion sections. Administered exams. Supervised and demonstrated experiments and techniques.

### EDUCATION:

M.S., University of Wisconsin-Milwaukee, 1986  
Major: Chemistry/Biochemistry  
Thesis: "Fluorescence Studies of E. coli tRNA<sup>phe</sup>, Magnesium and Spermine Effects on Solution Structure"

B.S., University of Wisconsin-Milwaukee, 1981  
Major: Chemistry



- PUBLICATIONS:** Kar, L, Lai, C.-S., Wolff, C.E., Nettesheim, D., Sherman, S. and Johnson, M.E. (1993)  $^1\text{H}$  NMR-based Determination of the Three-dimensional Structure of the Human Plasma Fibronectin Fragment Containing Inter-chain Disulfide Bonds. *The Journal of Biological Chemistry*, 268, 8580-8589.
- Lai, C.-S., Wolff, C.E., Novello, D., Griffone, L., Cuniberti, C., Molina, F. and Rocco, M. (1993) Solution Structure of Human Plasma Fibronectin under Different Solvent Conditions: Fluorescence Energy Transfer, Circular Dichroism and Light-scattering Studies. *Journal of Molecular Biology*, 230, 625-640.
- Wolff, C.E. and Lai C.-S. (1990) Intersulphydryl Distances in Plasma Fibronectin Determined by Fluorescence Energy Transfer: Effect of Environmental Factors. *Biochemistry*, 29, 3354-3361.
- Wolff, C. and Lai, C.-S. (1989) Fluorescence Energy Transfer Detects Changes in Fibronectin Structure upon Surface Binding. *Archives of Biochemistry and Biophysics*, 268, 536-545.
- Wolff, C. and Lai, C.-S. (1988) Evidence That the Two Amino Termini of Plasma Fibronectin Are in Close Proximity: A Fluorescence Energy Transfer Study. *Biochemistry*, 27, 3483-3487.
- Lai, C.-S., Homandberg, G., Mizioro, H., and Wolff, C. (1987) Tryptophan Fluorescence Studies of Plasma Fibronectin: Effects of Environmental Factors. *Biopolymers*, 26, 1381-1389.

**AFFILIATIONS:** American Chemical Society

**RADIATION TRAINING:** One semester course (Botany 540 - Bionucleonics) at University of Wisconsin-Milwaukee (Fall 1982). Course in radioisotope techniques and safety covering:

- Physical principles and principles of radiation protection
- Mathematical calculations pertaining to radioactivity
- Instrumentation and measurement techniques
- Biological effects of radiation
- Regulatory aspects

**RADIATION EXPERIENCE:** (1983-1986) **University of Wisconsin-Milwaukee, Dept. of Chemistry**  
Graduate research included enzyme assays using  $^3\text{H}$ .

(1991-Present) **Pharmacia Biotech, Inc.**

- Performed enzyme assays using  $^3\text{H}$  and  $^{32}\text{P}$ .
- Ran DNA/RNA sequencing gels using  $^{32}\text{P}$ .
- Performed meter surveys and wipe tests.
- Set up scintillation counter programs.
- Wrote Standard Operating Procedure for use of our scintillation counter.

Total usage:  $^3\text{H}$  - 50  $\mu\text{Ci}$   
(approximate)  $^{32}\text{P}$  -- 25 mCi

UNITED STATES NUCLEAR REGULATORY COMMISSION  
REGION III  
CONVERSATION RECORD

(X) TELEPHONE ( ) INCOMING ( ) CONVERSATION TIME 4pm DATE 9/25/96  
( ) OUTGOING

NAME OF PERSON(S) CONTACTED ORGANIZATION TELEPHONE NO.  
Edward Adolphson  
Parmacia Biotech Inc.

SUBJECT  
Amendment request to add an authorized user and to delete a lab.

SUMMARY

In order to complete the review, I need the following additional information:

1. The training and experience documenatation submitted for Ms. Girschner does not indicate she has any experience handling radioactive material. In order to use or supervise the use of radioactive material, an individual must obtain experience handling material under the supervision of an authorized user. Therefore, either document her experience handling experience or I can add her to the license after she has obtained actual experience for 3 months under the supervision of an authorized user.
2. Please describe the training provided to Ms. Girschner in terms of the number of hours in radiation safety training that was provided.

ACTION REQUIRED

ACTION TAKEN

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

September 16, 1996

Edward J. Adolphson  
Radiation Safety Officer  
Pharmacia Biotech Incorporated  
Molecular Biology Reagents Division  
2202 North Bartlett Avenue  
Milwaukee, WI 53202

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter Dated 08/29/96)

Dear Licensee:

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

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

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

It appears that your request is routine (see 1-3 below, as applicable).

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

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

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

Nuclear Materials Support Branch

Mail Control No. 301826  
License No. 48-14075-01