

Genetics Institute

June 28, 1988

Glenda Jackson
License Fee Management Branch
NRC - Region 1
475 Allendale Road
King of Prussia, PA 19406

re: Control Number 109045

Dear Ms. Jackson,

Genetics Institute hereby requests the following amendments to Materials License Number 20-20670-01.

- * The release of Genetics Institute's laboratories at One Ledgemont Center for unrestricted use and the removal of One Ledgemont Place from our NRC License.

In a letter dated June 6, 1988, Genetics Institute provided close-out survey data of the laboratories at One Ledgemont Center to support this request. This entire letter is enclosed as Attachment 1.

- * Permission to possess and use 50 mCi of Iodine 131. A description of how this material is intended to be used is provided in Attachment 2.

At this time, I also wish to update NRC on the current membership of Genetics Institute's Radiation Safety Committee. The current members are:

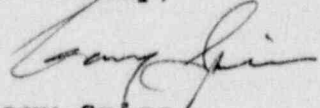
- | | |
|-------------------------|---|
| Jane Aghajanian | Research Staff, Genetics Institute |
| Judy Gordon | Quality Control Specialist,
Genetics Institute |
| Frank Masse | Radiation Safety Consultant |
| Gary Spies | Radiation Safety Officer,
Genetics Institute |
| John Tummino | Health and Safety Technician,
Genetics Institute |
| Katherine Turner, Ph.D. | Staff Scientist, Genetics Institute |

Also enclosed is a check for \$120 to cover the 3M amendment fee.

If questions arise regarding the above requests, please contact me.

9001310498 881112
REG1 LIC30
20-20670-01 PDR

Sincerely,



Gary Spies
Manager, Health and Safety

Attachments

87 CambridgePark Drive
Cambridge, Massachusetts 02140
Telephone: (617) 876-1170
FAX: (617) 876-1178
Mailback: GENETICS INBSN

109045
7-6-88

"OFFICIAL/ONE COPY" COPY MLTB

Genetics Institute

June 6, 1988

Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

To Whom To May Concern,

Genetics Institute Inc. hereby requests that the laboratories leased by us at One Ledgemont Center, Lexington, Massachusetts, be released for unrestricted use and that One Ledgemont Center, Lexington, Massachusetts be removed from our NRC License (Number 20-20670-01).

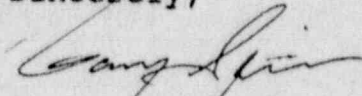
Genetics Institute applied for, in a letter dated March 5, 1987, and was subsequently granted on April 7, 1987, permission to use licensed material in leased laboratories at One Ledgemont Center, Lexington, Massachusetts. As of May 31, 1988, Genetics Institute relocated all these laboratories to One Burtt Road, Andover, Massachusetts, and completely moved out of One Ledgemont Center.

As stated in the March 5, 1987 request, two laboratories used radioactive material in the Lexington laboratories. One used 5 mCi or less of S-35 infrequently, the other used small quantities (less than 1 mCi) of proteins labeled with H-3, C-14, or I-125.

The attached survey was performed in accordance with the July, 1982 "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use". The survey, which was performed on May 31, 1988 and encompassed the entire facility leased by Genetics Institute, found no areas of radioactive contamination. It is our understanding that these laboratories will be leased to new tenants shortly.

If questions arise regarding this report or any aspect of Genetics Institute's radiation safety program, please contact me.

Sincerely,



Gary Spies
RSO

Attachment

GS/drck

87 CambridgePark Drive
Cambridge, Massachusetts 02140
Telephone (617) 876-1170
Telex 948219 Answerback GENETICS INBSN

Release Survey of the
Laboratories Leased by
Genetics Institute
at One Ledgemont Center,
Lexington, Massachusetts

Introduction and Scope

A final survey for radioactive contamination was performed on May 31, 1988 in accordance with the July 1982 Guidelines. Figure 1 is a floor plan of the entire facility leased by Genetics Institute at One Ledgemont Center. Hatched areas designate the areas surveyed with a low range survey meter. The numbers correspond to areas wipe-surveyed for removable contamination.

Figure 2 is the scintillation counter report of the wipe surveys. The SAM column corresponds to the numbers on Figure 1. The DPM/100 cm² column is obtained by subtracting background from CPM and dividing by the efficiency of that particular channel.

Procedure

1) Survey by Meter

All laboratory benches, hoods, and sinks and the floor in the hatched area of Figure 1 was first surveyed with a Ludlum Model 3 survey meter with a Ludlum Model 44-9 "Pancake" Geiger-Muller probe. The instrument has been calibrated by F.X. Masse Associates within the past 6 months to measure mrem per hour with an accuracy of 10% on all scales.

Result

No radiation levels above background were detected.

2) Wipe Survey for Removable Contamination

100 cm² of surface was wiped with a piece of absorbant tissue. Surfaces wiped are noted on Figure 1. Tissues were counted on a Beckman Model 6800 Scintillation Counter. The instrument has been programmed to split its entire range into three channels.

Channel 1 counts primarily H-3 at 45.855% efficiency

Channel 2 counts C-14 at 76.5% efficiency

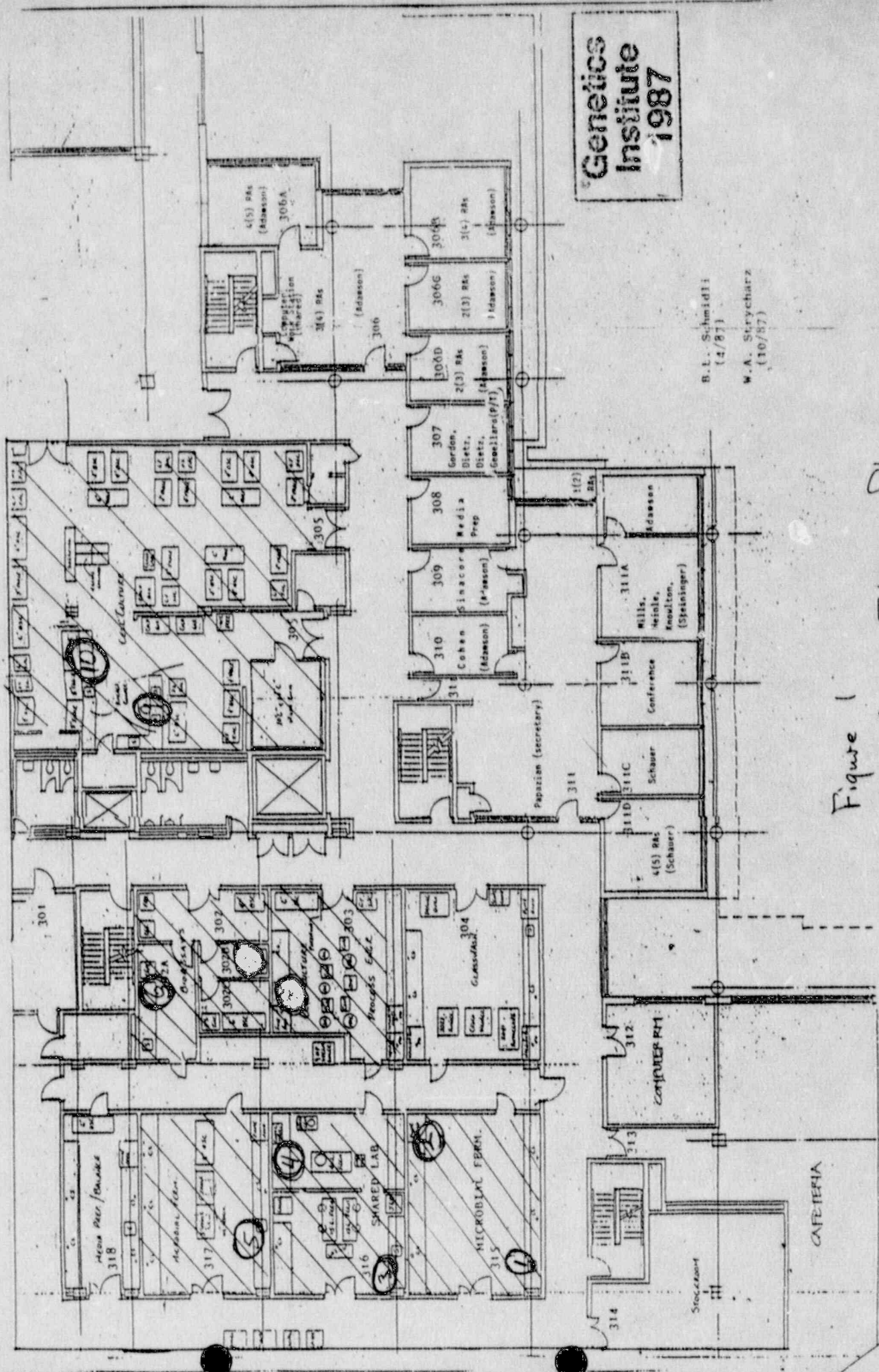
Channel 2 also counts S-35 at 89.6% efficiency

Channel 3 has been programmed to count I-125
at 33.7% efficiency.

Results

All results are well within the limits published in Table 1 of the July 1982 Guidelines and, statistically, cannot be distinguished from background.

Note: The limit for removable contamination published in Table 1 of the Guidelines for beta-gamma emitters is 1000 dpm per 100 cm².



Genetics
Institute
1987

B.L. Schmidt
(4/87)
W.A. Strycharz
(10/87)

Figure 1
Laboratory Floor Plan

Figure 2
Wipe Data

USER:10 ID:RAD SAFETY PRESET TIME: 1.00 FRI 03 JUN 1988 11:55
 SAMPLE REPEAT: 1 CYCLE REPEAT: 1 SCR:N RS232:N
 H#: 1 ADC:N DCF:N RCM:N
 CHANNEL 1-LL: 0 UL: 400 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 CHANNEL 2-LL:400 UL: 670 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 CHANNEL 3-LL:670 UL:1000 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 DATA CALC: CPM, UNKNOWN REPLICATES: 1 NORM FACTOR:01.00000
 HALF LIFE(DAYS):N

SAM	POS	CH	$\frac{DPM}{\mu\text{m}^2}$	CPM	2SIG%	TIME	EL TIME	AVG H#	ERR
1	32	1	30.5	26.00	39.22	1.00	1.28	102.0	
		2	2.2	13.00	55.47				
		3	0	12.00	57.74				
2	33	1	115.6	65.00	24.81	1.00	2.52	102.0	
		2	32.2	40.00	31.62				
		3	0	18.00	47.14				
3	34	1	17.4	20.00	44.72	1.00	3.75	82.0	
		2	5.6	16.00	50.00				
		3	0	16.00	50.00				
4	35	1	45.7	33.00	34.82	1.00	4.98	99.0	
		2	4.4	15.00	51.64				
		3	0	11.00	60.30				
5	36	1	58.9	39.00	32.03	1.00	6.21	98.0	
		2	0	10.00	63.25				
		3	0	12.00	57.74				
6	37	1	17.4	20.00	44.72	1.00	7.43	94.0	
		2	2.2	13.00	55.47				
		3	0	13.00	55.47				
7	38	1	30.5	26.00	39.22	1.00	8.77	133.0	
		2	0	9.00	66.67				
		3	0	8.00	70.71				
8	39	1	21.8	22.00	42.64	1.00	10.00	105.0	
		2	1	12.00	57.74				
		3	0	12.00	57.74				
9	40	1	34.8	28.00	37.80	1.00	11.34	110.0	
		2	2.2	13.00	55.47				
		3	0	6.00	81.65				
10	41	1	17.4	20.00	44.72	1.00	12.67	94.0	
		2	7.2	13.00	55.47				
		3	0	7.00	75.59				

Back ground CPM
 channel 1 12.0
 channel 2 11.0
 channel 3 21.0

June 28, 1988
Amendment Request
Lic. No. 20-20670-01
Attachment 2

Request to Possess up to 50 milliCuries of Any Chemical and/or
Physical Form of Iodine 131

A new area of research at Genetics Institute requires the use of Iodine 131 labeled proteins in biotransport and biological half-life studies using laboratory rats, mice and rabbits. All use of this isotope will be performed in accordance with "Required Procedures for Radiation Protection" submitted February 2, 1984 and will all subsequent license conditions.

This research involves administering Iodine 131 labeled proteins to laboratory rats, mice and rabbits and studying the pharmacokinetics of the protein. We require Iodine 131 in addition to Iodine 125 in order to compare the pharmacokinetics of two proteins administered simultaneously to one laboratory animal. All uses and disposal practices will comply with the conditions of Genetics Institute's License and with all NRC regulations, particularly 10 CFR 20.

During procedures involving the use of Iodine 131, a Ludlum model 3 survey meter with a model 44-7 Geiger-Mueller Probe will be operating. This meter will be calibrated biannually by F.X. Masse Associates.

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER John M. Tummino	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
---	--

3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Harvard School of Public Health (March 28-April, 1988)	1 Five-Day	Course
b. RADIATION PROTECTION	Harvard School of Public Health (March 28-April, 1988)	1 Five-Day	Course
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Harvard School of Public Health (March 28-April, 1988)	1 Five-Day	Course
d. RADIATION BIOLOGY	Harvard School of Public Health (March 28-April, 1988)	1 Five-Day	Course
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Judy A. Gordon	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
--	--

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE (S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	May 1978, Harvard Safety Training October 1984, Genetics Institute Radiation Safety	8 1	
b. RADIATION PROTECTION	May 1978, Harvard Safety Training October 1984, Genetics Institute Radiation Safety	8 1	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	May 1978, Harvard Safety Training October 1984, Genetics Institute Radiation Safety	8 1	
d. RADIATION BIOLOGY	May 1978, Harvard Safety Training October 1984, Genetics Institute Radiation Safety	8 1	
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-125	20 mCi	Dana Farber Cancer Institute	April 1978 - September 1984	In-vitro protein-labeling
H-3	100 mCi	Dana Farber Cancer Institute	April 1978 - September 1984	In-vivo labeling

Genetics Institute

030-20701

June 6, 1988

Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

To Whom To May Concern,

Genetics Institute Inc. hereby requests that the laboratories leased by us at One Ledgemont Center, Lexington, Massachusetts, be released for unrestricted use and that One Ledgemont Center, Lexington, Massachusetts be removed from our NRC License (Number 20-20670-01).

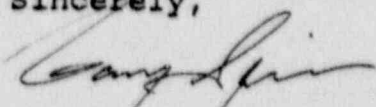
Genetics Institute applied for, in a letter dated March 5, 1987, and was subsequently granted on April 7, 1987, permission to use licensed material in leased laboratories at One Ledgemont Center, Lexington, Massachusetts. As of May 31, 1988, Genetics Institute relocated all these laboratories to One Burtt Road, Andover, Massachusetts, and completely moved out of One Ledgemont Center.

As stated in the March 5, 1987 request, two laboratories used radioactive material in the Lexington laboratories. One used 5 mCi or less of S-35 infrequently, the other used small quantities (less than 1 mCi) of proteins labeled with H-3, C-14, or I-125.

The attached survey was performed in accordance with the July, 1982 "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use". The survey, which was performed on May 31, 1988 and encompassed the entire facility leased by Genetics Institute, found no areas of radioactive contamination. It is our understanding that these laboratories will be leased to new tenants shortly.

If questions arise regarding this report or any aspect of Genetics Institute's radiation safety program, please contact me.

Sincerely,


Gary Spies
RSO

Attachment

GS/drck

Jun 14 1988
82991
#120
317
And
7/18/88
7/18/88
S. Kenney

87 Cambridge Park Drive
Cambridge, Massachusetts 02140
Telephone: (617) 876-1170

109045
6-9-88

"OFFICIAL RECORD COPY" GENETICS INBSN

Release Survey of the
Laboratories Leased by
Genetics Institute
at One Ledgeмонт Center,
Lexington, Massachusetts

Introduction and Scope

A final survey for radioactive contamination was performed on May 31, 1988 in accordance with the July 1982 Guidelines. Figure 1 is a floor plan of the entire facility leased by Genetics Institute at One Ledgeмонт Center. Hatched areas designate the areas surveyed with a low range survey meter. The numbers correspond to areas wipe-surveyed for removeable contamination.

Figure 2 is the scintillation counter report of the wipe surveys. The SAM column corresponds to the numbers on Figure 1. The DPM/100 cm² column is obtained by subtracting background from CPM and dividing by the efficiency of that particular channel.

Procedure

1) Survey by Meter

All laboratory benches, hoods, and sinks and the floor in the hatched area of Figure 1 was first surveyed with a Ludlum Model 3 survey meter with a Ludlum Model 44-9 "Pancake" Geiger-Muller probe. The instrument has been calibrated by F.X. Masse Associates within the past 6 months to measure mrem per hour with an accuracy of 10% on all scales.

Result

No radiation levels above background were detected.

2) Wipe Survey for Removeable Contamination

100 cm² of surface was wiped with a piece of absorbant tissue. Surfaces wiped are noted on Figure 1. Tissues were counted on a Beckman Model 6800 Scintillation Counter. The instrument has been programmed to split its entire range into three channels.

Channel 1 counts primarily H-3 at 45.855% efficiency

Channel 2 counts C-14 at 76.5% efficiency

Channel 2 also counts S-35 at 89.6% efficiency

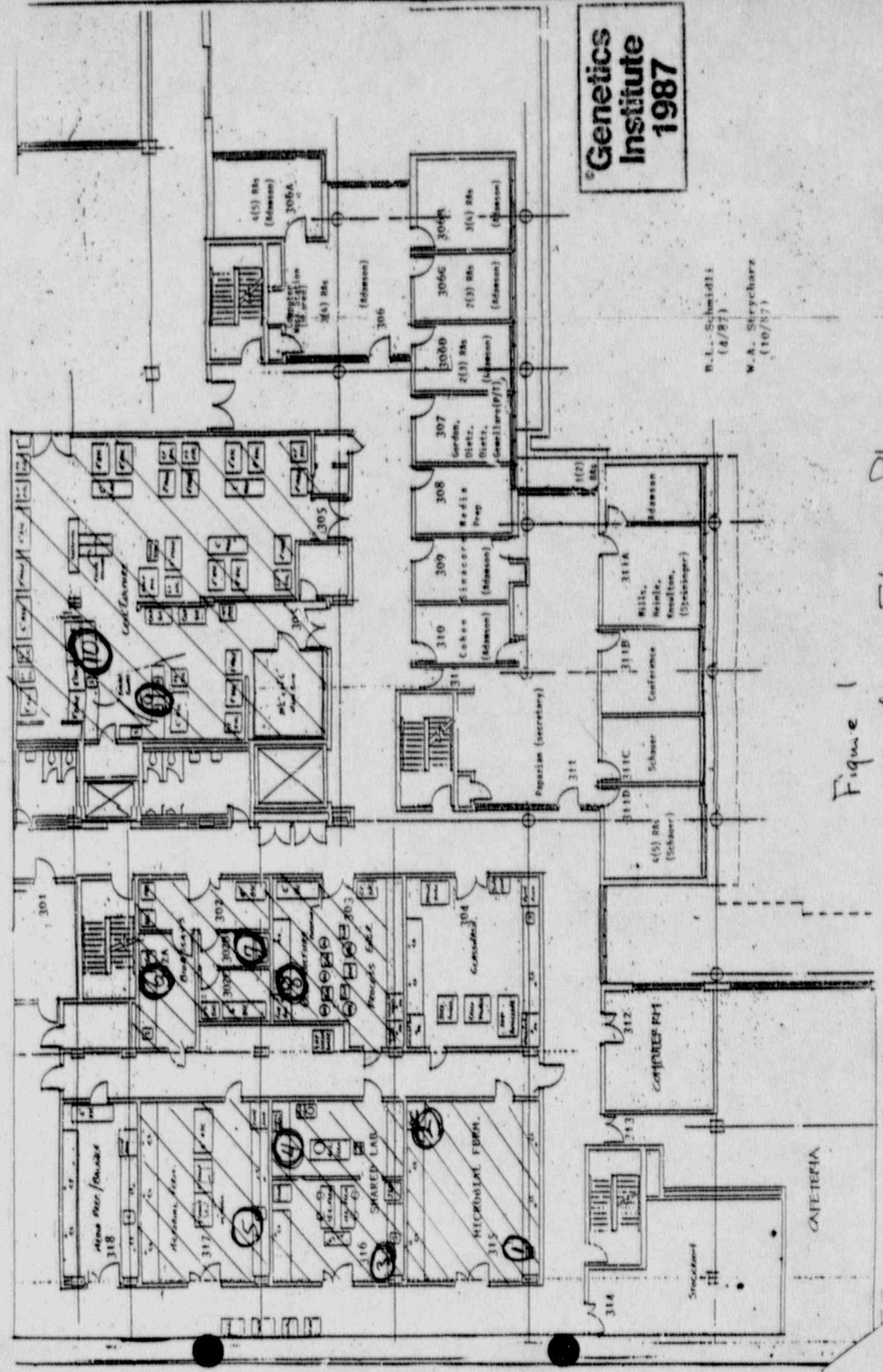
Channel 3 has been programmed to count I-125
at 33.7% efficiency.

Results

All results are well within the limits published in Table 1 of the July 1982 Guidelines and, statistically, cannot be distinguished from background.

Note: The limit for removeable contamination published in Table 1 of the Guidelines for beta-gamma emitters is 1000 dpm per 100 cm².

**Genetics Institute
1987**



D.L. Schmidt
(4/87)
W.A. Strycharz
(10/87)

Figure 1
Laboratory Floor Plan

Figure 2
Wipe Data

USER:10 ID:RAD SAFETY PRESET TIME: 1.00 FRI 03 JUN 1988 11:55
 SAMPLE REPEAT: 1 CYCLE REPEAT: 1 SCR:N RS232:N
 H#: 1 AQC:N QCF:N RCM:N
 CHANNEL 1-LL: 0 UL: 400 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 CHANNEL 2-LL:400 UL: 670 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 CHANNEL 3-LL:670 UL:1000 2SIGMA: 2.00 BKG SUB: 0.00 BKG 2SIG: 0.00 LSR: 0
 DATA CALC: CPM, UNKNOWN REPLICATES: 1 NORM FACTOR:01.00000
 HALF LIFE(DAYS):N

SAM	POS	CH	$\frac{DPM}{UL}$	CPM	2SIG%	TIME	EL TIME	AVG H#	ERR
1	32	1	30.5	26.00	39.22	1.00	1.28	102.0	
		2	2.2	13.00	55.47				
		3	0	12.00	57.74				
2	33	1	115.6	65.00	24.81	1.00	2.52	102.0	
		2	32.2	40.00	31.62				
		3	0	18.00	47.14				
3	34	1	17.4	20.00	44.72	1.00	3.75	82.0	
		2	5.6	16.00	50.00				
		3	0	16.00	50.00				
4	35	1	45.7	33.00	34.82	1.00	4.98	99.0	
		2	4.4	15.00	51.64				
		3	0	11.00	60.30				
5	36	1	58.9	39.00	32.03	1.00	6.21	98.0	
		2	0	10.00	63.25				
		3	0	12.00	57.74				
6	37	1	17.4	20.00	44.72	1.00	7.43	94.0	
		2	2.2	13.00	55.47				
		3	0	13.00	55.47				
7	38	1	30.5	26.00	39.22	1.00	8.77	133.0	
		2	0	9.00	66.67				
		3	0	8.00	70.71				
8	39	1	21.8	22.00	42.64	1.00	10.00	105.0	
		2	1	12.00	57.74				
		3	0	12.00	57.74				
9	40	1	34.8	28.00	37.80	1.00	11.34	110.0	
		2	2.2	13.00	55.47				
		3	0	6.00	81.65				
10	41	1	17.4	20.00	44.72	1.00	12.67	94.0	
		2	2.2	13.00	55.47				
		3	0	7.00	75.59				

Back ground cpm
 channel 1 12.0
 channel 2 11.0
 channel 3 21.0

archos, inc.

P.O. Box 2273 Cambridge, Ma. 02238 (617) 492-8621

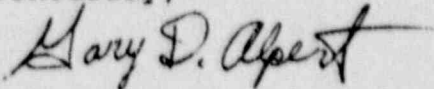
June 1, 1988

Gary Spies
Regulatory Affairs Officer
Genetics Institute
87 Cambridge Park Drive
Cambridge, MA 02140

Dear Gary,

The Ledgemont Research Center in Lexington is free of rodent and insect infestation. This assessment is based upon our extensive use of sticky traps, reports from staff and monthly inspections by our service technicians. There has been no evidence of pests in laboratories, restrooms and food service areas since we have been monitoring this facility. This pest free condition has been documented to your office as part of our monthly pest report.

Sincerely,



Gary D. Alpert, Ph.D.
Entomologist

cc. David Welch

"OFFICIAL RECORD COPY" **MLT**

109045

JUN 23 1988

Genetics Institute
ATTN: Mr. Gary Spies
Radiation Safety Officer
87 Cambridge Park Drive
Cambridge, MA 02140

Gentlemen:

This refers to your letter dated June 6, 1988, requesting that space at One Ledgemont Center be released for unrestricted use.

It will be necessary to amend Materials License 20-20670-01 to make this change, for which an amendment fee of \$120 is required as specified in §170.31 (3M) of 10 CFR 170, copy enclosed. Payment should be made to the U.S. Nuclear Regulatory Commission and mailed to my attention at our Washington, D.C. address.

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406. The fee, however, is required prior to issuance of the amendment. When submitting the fee, please refer to CONTROL NUMBER 109045.

Sincerely,

Signed by:
Glenda Jackson

Glenda Jackson
License Fee Management Branch
Division of Accounting and Finance
Office of Administration and
Resources Management

Enclosure:
10 CFR 170

cc: Region I

DISTRIBUTION:
Pending Fee File
ARM/DAF R/F
LFMB R/F (2)
DW/RI/Genetics

OFFICE: ARM/LFMB *mm*
SURNAME: MMessier:rej
DATE: 6/22/88

ARM/LFMB ✓
GJackson
6/22/88

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: 19890531
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GENETICS INSTITUTE
RECEIVED DATE: 880609
DOCKET NO: 3020701
CONTROL NO.: 109045
LICENSE NO.: 20-20670-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: 0

3. COMMENTS
*Note addl requests
in Jan. 28, 1988 letter.*

SIGNED BP
DATE 6/15/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1/1)

1. FEE CATEGORY AND AMOUNT: 3M \$120

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

3. OTHER _____

SIGNED J. Kimberley
DATE 7/18/88