LAHEY CLINIC MEDICAL CENTER
41 MALL ROAD
BURLINGTON, MASSACHUSETTS 01805

ROBERT E. WISE, M.D.
CHIEF EXECUTIVE OFFICER
CHAIRMAN, BOARD OF GOVERNORS

AREA CODE 617 273-5100
CABLE ADDRESS "LAHEYCLIN"

February 13, 1985

RECEIVED BY LFMB
Date. 3/6/85
Log. March 5 I
By. Brown
Orig. To.
Action Compl. 3/22/85

John E. Glenn, Ph.D., Chief
Nuclear Materials Section B
Nuclear Regulatory Commission
Division of Engineering and Technical
Programs
631 Park Avenue
King of Prussia, PA 19406

Dear Dr. Glenn:

This letter requests amendments to our materials license #20-05766-02, amendment number 35 "Corrected Copy" date December 13, 1984.

Please add to our list of authorized users Sanford R. Kurtz, M.D. as a user authorized for in vitro studies. With this letter I am submitting the completed NRC form 313M basic physics of radioisotopes, and a letter signed by Edward W. Webster, Ph.D. certifying successful completion of the basic course in radioisotopes dated June 1974. With the inclusion of Dr. Kurtz as an authorized user please delete Harvey George, Ph.D. from our license as an authorized user.

With this letter I am also submitting a revised "Procedures and Precautions for the Use of Xenon-133 Gas", a revision dated January 1985. This amended procedure replaces our submission of July 1980.

At this time we also wish to note several changes in room use as controlled areas. We wish to delete Room 2-707 "Radioisotope Handling and Counting Room", Room 7-010 "Radioisotope Preparation Room", and Room 6-007 "Radioisotope Work Site" as controlled areas. In addition, I am submitting a floor plan of clinical laboratory Room 3G-13, the present radioassay laboratory room. This room is now being used for radioimmunoassay tests and replaces Room 3G-1 as described in our submission of July 1980.

At this same time I wish to note that in the near future the existing radioimmunoassay laboratory in Room 3G-13 will be moved to Room 3G-9, the room shown in the plan submitted with this letter.

The outline of the controlled areas for these rooms is highlighted in black on the area plan.

Applicant.....
Check No. 10602
Amount Fee Cat. $120.00
Type of Fee Amendment
Date Check Rec'd 3/7/85
Received By
LAHEY CLINIC FOUNDATION, INC.

"OFFICIAL RECORD COPY"
ML10 03479

MARY AND ARTHUR R. CLAPHAM HOSPITAL
OPERATED BY
LAHEY CLINIC HOSPITAL, INC.

CHARLES A. DANA AMBULATORY CARE CENTER
OPERATED BY
LCF FOUNDATION, INC.

8506180572 850523
REG1 LIC30
20-05766-02 PDR

FEB 28 1985

Furthermore, we wish to consolidate our radiation storage in the Radiotherapy Department in the Cesium-137 storage work area shown in the accompanying submission. The only addition as this time is that we will also store the Strontium-90 eye applicator and calibration sources in this room with the Cesium sources.

If you have any questions about this submission, please call the Radiation Safety Officer, Robert S. Wenstrup, Ph.D. at (617) 273-8166.

Sincerely,

Robert E. Wise, M.D.

REW:mmc

RECEIVED
'85 MAR -6 P2:42

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Sanford R. Kurtz, M.D.	MA, CA, CO

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Blood Banking-Immunohematology		1977
Pathologic Anatomy		1975
Clinical Pathology		1975
Diplomate, National Board of Medical Examiners		1972

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Harvard Medical School, MGH New England Roentgen Ray Society February 20, 1974-June 5, 1974		
b. RADIATION PROTECTION	"		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	30	10
d. RADIATION BIOLOGY	"		
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
^{125}I	100 uCi	Naval Blood Research Lab	1975-present	Cell Labeling
^{51}Cr	400 uCi	Naval Blood Research Lab	1975-present	Cell Labeling
DF ^{32}P	200 uCi	Naval Blood Research Lab	1975-present	Cell Labeling
Indium-111	1mCi	Naval Blood Research Lab	1975-present	Cell Labeling

The New England Roentgen Ray Society

Hereby certifies that

Sanford Hurtz, M.D.

Has pursued a course of study sponsored by this society covering the basic physics of radioisotopes with particular emphasis on their medical applications and has successfully completed the required studies, laboratory exercises, and examinations.

On this 14th *day of* June *1974* .

President

Wilson E. Woodall
Secretary

E. W. Webster
Course Director

HARVARD MEDICAL SCHOOL ⟡ MASSACHUSETTS GENERAL HOSPITAL

DEPARTMENT OF RADIOLOGY
Division of Radiological
Sciences and Technology

Mailing Address:

Massachusetts General Hospital
Boston, Massachusetts 02114
(617) 726-8326
if no answer: 726-303

June 14, 1974

To whom it may concern:

This is to certify that

Sanford Kurtz, M.D.

successfully completed the Basic Course in Radioisotopes sponsored by the New England Roentgen Ray Society and directed by the undersigned during the period February 20, 1974 to June 5, 1974. The course consisted of 30 class hours including the performance of five experiments and covered basic material relating to the nature and properties of radioactivity, radioisotope production, radiation dosimetry, the measurement of radioactivity, the biological effects of radiation and methods for the safe handling of radioisotopes.

E. W. Webster

E. W. Webster, Ph.D.
Course Director
Associate Professor of Radiology

d

PROCEDURES AND PRECAUTIONS FOR USE OF XENON-133 GAS

Xenon-133 gas will be used to perform pulmonary ventilation studies. We request a possession limit of 400 mCi of Xenon-133. A maximum of 10 patient studies per week (520 per year) will be performed using an average dose of 20 mCi per procedure. Higher doses will be used only when professional medical judgement indicates it to be necessary.

All doses for patient use will be checked immediately prior to administration with the dose calibrator. The radiological safety equipment and procedures are the same as those described elsewhere in our license submission. They will be followed in addition to the special procedures described in this addendum.

The radiopharmaceutical will be supplied by NPI or New England Nuclear Corporation. This product has NDA status with the Food and Drug Administration. The special equipment to be used in conjunction with our Gamma Cameras are listed below, and copies of the manufacturers' literature is attached.

1. Calidose Dispenser Delivery System; Refer to Attachment 1.
2. Pulmonex Xenon System.
3. "Xen Alert" 133 Xe Room Air/Trap Monitor; Nuclear Associates. Refer to attachment 4.

Xenon-133 Storage

The Xenon-133 gas will be stored in its lead shipping container within the storage cave located in the Nuclear Medicine radiopharmacy ("hot lab"). A description of this room, the storage cave, work area, fume hood, radiation monitoring equipment, dose calibrator and radiological safety procedures are the same as those described elsewhere in our license submission. The exhaust hood is designed to draw 500 CFM face velocity variable from 65 ft./min. to 125 ft./min. The exhaust hood opening is 8 sq. ft. The total volume of the room is approximately 910 cu. ft.

Air is also drawn from the room through an 81 in.^2 ceiling exhaust duct drawing 120 cu. ft./min.

Air enters the room through a ceiling supply vent and through the door. Exhaust is through the ceiling vent and fume hood. The room is kept at a slight negative pressure when the hood fan is not operating; and at a substantial negative pressure when the hood is operating. the maximum concentration of Xenon-133 over forty hours in seven consecutive days for this Restricted Area is calculated to 1.19 X 10^-6 μCi/ml (refer to attachment 5) which is below the NRC MPC of 1 X 10^-5 μCi/ml as stated in Section 20.103 10 CFR Part 20 and Schedule B Table I of Part 20.

In the event of an inadvertent release of the Xenon-133 in this storage area, the following emergency procedure will be implemented: all personnel will leave the room and

the door will be closed; the room will remain unoccupied for 15 minutes and will be surveyed with a low level survey meter, immediately upon re-entry,, to insure that the radiation levels have returned to normal for the area. A volume of air equal to 11.3 times the room's capacity will be exchanged during this 15 minute period as shown in the calculation below:

a. Volume of room = 810 cu. ft.
b. Air flow volume = 610 cu. ft./min.
c. Time - 15 minutes

Therefore: $\frac{610 \times 15}{810}$ = 11.3 times

Imaging Room 2H-8

All Xenon-133 lung ventilation procedures will be performed in the Rooms 2H-7 and 2H-8. Air enters each room through two ceiling ducts and the door. The air leaves the room via two 81 sq. inch ceiling vents drawing 280 cu. ft./min. each (total of 560 cu. ft./min. for each room). The total volume of each imaging room is 2965 cu. ft. The maximum concentration of Xenon-133 over forty hours in seven consecutive days for this Restricted Area is calculated to be 2.6 X 10^-6 μCi/ml (refer to Attachment A) which is below the NRC MPC of 1 X 10^-5 μCi/ml as stated in Section 20.1003 10 CFR Part 20 and Schedule B Table 1 of Part 20.

In the event that there is an inadvertent release of Xenon-133 in either Room 2H-7 or 2H-8 the following emergency procedure will be implemented: The patient will be removed from the room; all personnel will leave the room and the door will be closed; the room will remain unoccupied for 60 minutes; upon re-entry, the room will be surveyed to insure the radiation levels have returned to normal. A volume of air equal to 11.4 times the capacity of the imaging room will be exchanged during this 60 minute period as shown in the calculation below.

a. Total volume of the imaging room = 2965 cu. ft.
b. Total air flow volume for the imaging room = 560 cu. ft./min.
c. Time = 60 minutes.

Therefore: $\frac{560 \times 60}{2965}$ = 11.4 times

Exhausted air from the imaging rooms (2H-7 and 2H-8) is released into a dedicated exhaust duct servicing the Nuclear Medicine module. Air is exhausted from the Radiopharmacy (2H-19) into this duct system, and is also exhausted through the fume hood to the outside air. The Nuclear Medicine release point is 14 in. above the roof and more than 100 ft. from all building air intakes. The fume hood exhaust release point is 24 inches above the roof and more than 100 ft. from all building air intakes. No other buildings are in the vicinity. The maximum concentration of Xenon-133 released from the Nuclear Medicine module exhaust system averaged over one year for this unrestricted area is 5.81 X 10^-8 μCi/ml (refer to Attachment 7); the corresponding concentration at the fume hood release point averaged over one year is 1.41 X 10^-7 μCi/ml (refer to Attachment 7). Both these

concentrations are below the NRC MRC of 3 X 10^-7 μCi/ml as stated in 10 CFR Section 20.106 and Schedule B, Table 2 and complies with 10 CFR Section 20.1 (c).

The Xenon-133 gas will be used in the following manner after confirming the dose by measurement in our dose calibrator. The unit dose will be loaded into the shielded Calidose Dispenser in the radiopharmacy. The patient will be instructed on the details of the procedure and will be told why his cooperation is needed. Just prior to the study with the Xenon-133 gas, one or more practice runs will be accomplished. The Calidose Dispenser will then be taken to the imaging area where the lung ventilation procedure will be performed. The dispenser will be connected to the mask which is used to prevent the patient from exhaling the Xenon-133 into the room. The lung ventilation procedure will be composed of the three standard phases of wash-in, equilibrium and washout. During the washout phase used Xenon-133 gas will be drawn directly into the Nuclear Associates Gas Trap.

Xenon levels in each imaging room will be monitored with a "Xen Alert Monitor" placed near the Xenon delivery system. During each ventilation study room air is continuously drawn into the counting chamber and monitored while the air is exchanged. An analog meter continuously displays fractions of the maximum permissible concentration (MPC) while two digital registers display integrated MPC-hours and total hours running time. The Xen Alert will be used whenever a Xenon study is being performed. After each study the registers will be read to record the exposure level in the area of the exam.

If the Xe-133 rate level rises abnormally or the digital registers indicate that the maximum permissible weekly MPC hours level has been reached, the room will be evacuated until the Xe-133 levels decrease to a low level.

The "Xen Alert" will also be used to monitor the "Pulmonex" Xenon trap efficiency. Records of the weekly gas trap effluent levels will be maintained. Trap cartridges will be replaced when indicated by Xen Alert measurements.

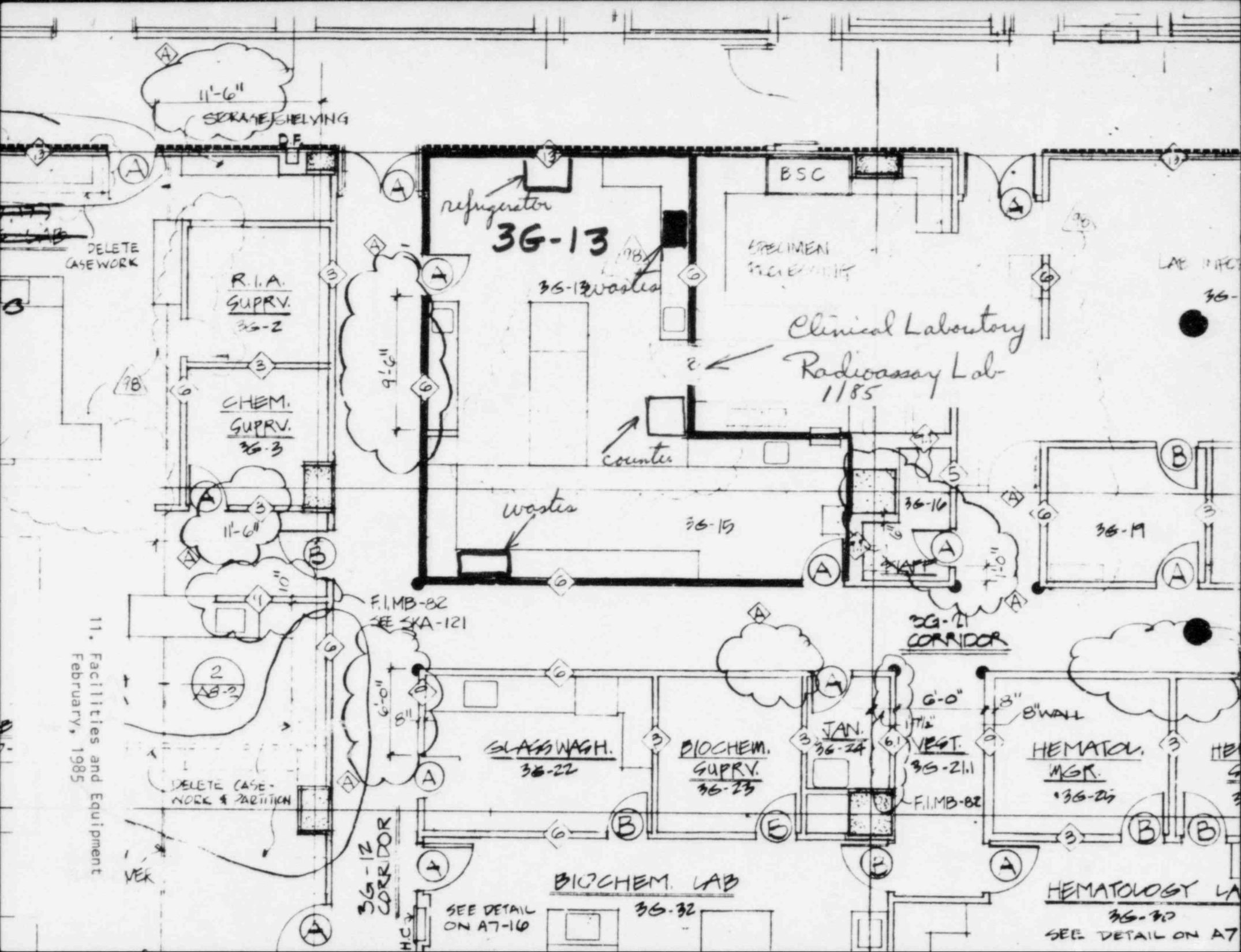
Saturated cartridges will be stored in the radioactive waste storage area and allowed to decay to background before disposal in the trash.

In order to insure that a minimum of Xenon 133 leakage occurs and that equipment works correctly, the following procedures will be followed:

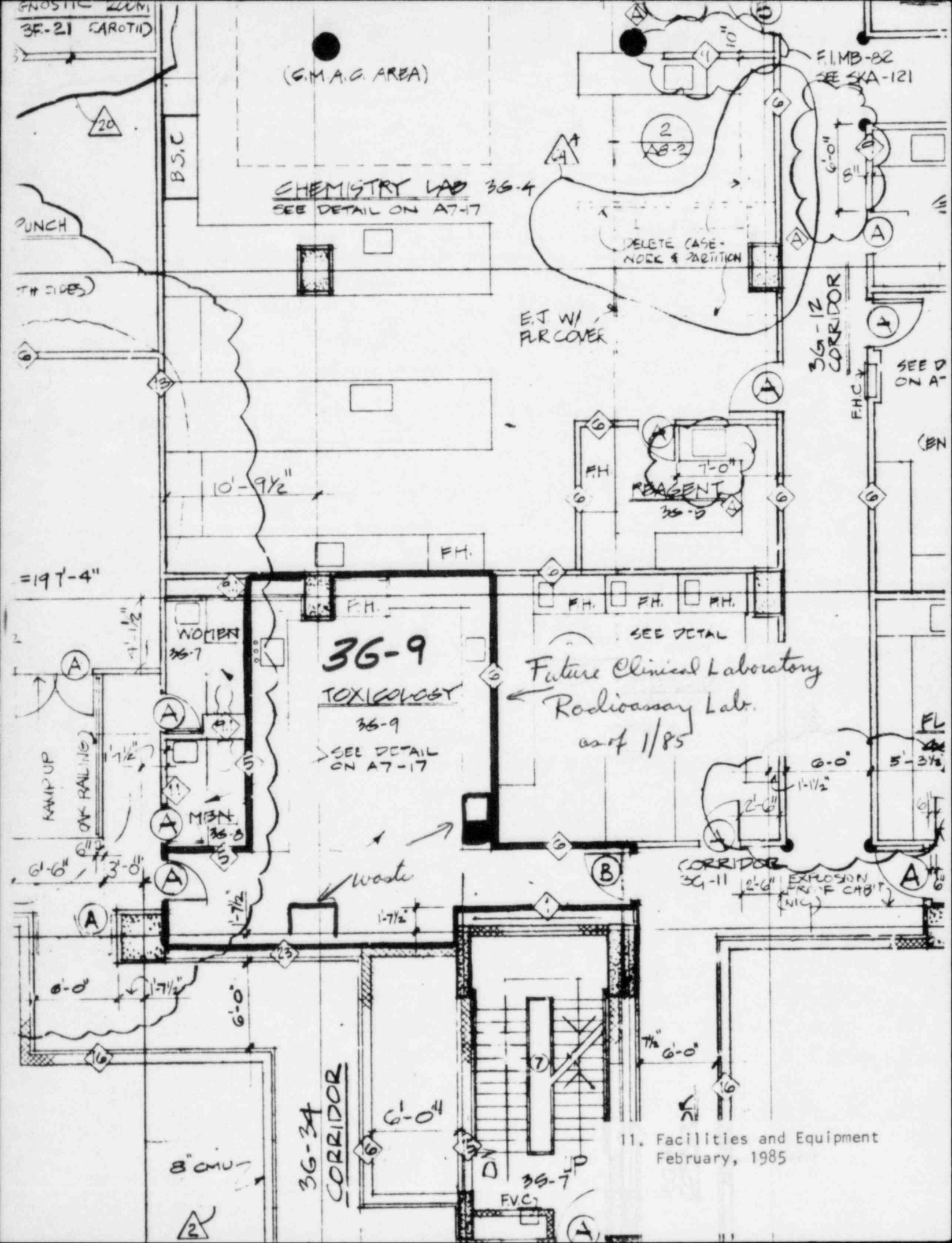
1. The Calidose Dispenser Delivery System will be checked prior to use to insure proper operation.
2. Pulmonex Xenon System will be checked at the beginning of each week by filling it with oxygen and checking for leakage. Its operation will be checked during the practice runs prior to administration of the Xenon-133 gas. The manufacturer's operating instructions will be followed and the carbon dioxide absorber will be replenished as needed.
3. The Xenon effluent level from the trap will be checked with Xen Alert system weekly.
4. All exhaust vents will be checked twice a year to confirm their continued efficiency. In addition, they will be checked whenever structural changes are made which would affect their efficiency. Records verifying these

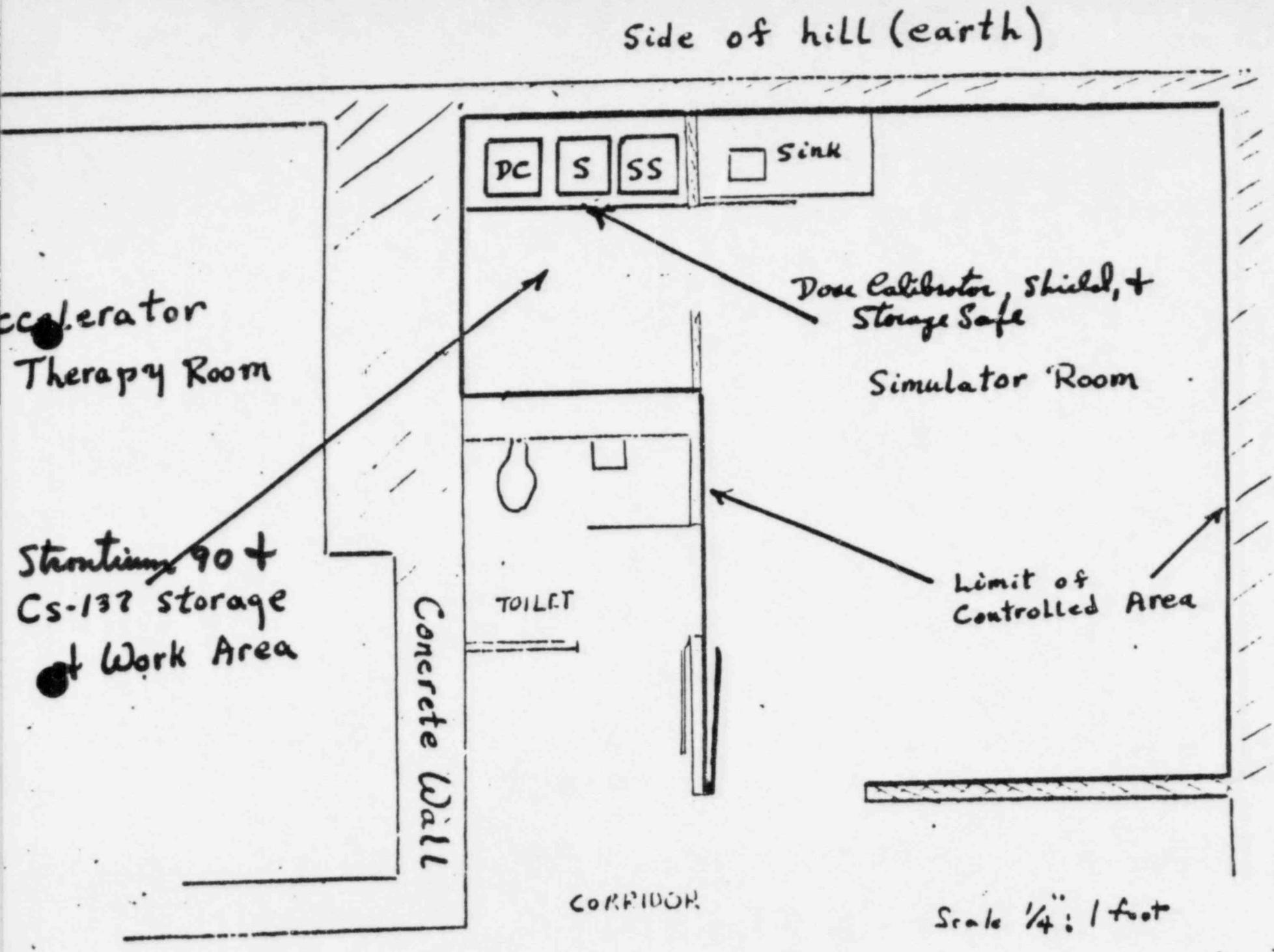
procedures will be maintained.

For further information concerning the ventilation system, please refer to floor plan and exhaust ventilation plan (Attachment 8).



11. Facilities and Equipment
February, 1985


(G.M.A.C. AREA)
CHEMISTRY LAB 36-4
SEE DETAIL ON A7-17
B.S.C.
PUNCH
DELETE CASE-WORK & PARTITION
E.J W/ FLR COVER
36-12 CORRIDOR
F.H.C.
10'-9½"
F.H.
REAGENT
36-5
=197'-4"
WOMEN
36-7
36-9
TOXICOLOGY
36-9
SEE DETAIL ON A7-17
SEE DETAL
Future Clinical Laboratory
Radioassay Lab.
as of 1/85
MEN
36-8
waste
CORRIDOR
36-11
EXPLOSION PROOF CABIT
(NIC)
36-34 CORRIDOR
8" CMU
36-7
F.V.C.
6'-0"
6'-6"
3'-0"
1'-7½"
1'-1½"
2'-6"
5'-3½"


Side of hill (earth)
DC
S
SS
Sink
Dose Calibrator, Shield, + Storage Safe
Simulator Room
Therapy Room
Strontium 90 + Cs-137 storage + Work Area
Concrete Wall
TOILET
Limit of Controlled Area
CORRIDOR
Scale 1/4" : 1 foot

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL Fee Needed

A. REGION 1

1. APPLICATION ATTACHED

Applicant/Licensee: Lahey Clinic Foundation

Application Dated: 2/13/85

Control No.: 03479

License No.: 20-05766-02

2. FEE ATTACHED

Amount: 0

Check No.: 0

3. COMMENTS

Signed Brenda P. Latchet

Date 3/1/85

8/31/89
1C

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: #120 - 7C

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

Amendment ✓

Renewal

License

Signed H Jackson

Date 3/22/85

REGION I FORM 213
(MARCH 1983)