

PINK COPY

MAR 15 1985

Leila Y. Post Montgomery Hospital
Radiology Department
ATTN: Donald F. Ryan
President
300 North Avenue
Battle Creek, MI 49016

SUBJECT: REQUEST FOR AN AMENDMENT TO LICENSE NUMBER 21-01354-03 DATED MARCH 23, 1984
AND OUR REQUEST FOR ADDITIONAL INFORMATION DATED DECEMBER 6, 1984
AND FOLLOW UP PHONE CONTACT ON JANUARY 7, 1985

Gentlemen:

We requested in the above mentioned letter that you respond to us within 30 days. A check of our files indicate that we have not received a response from you to date.

You are hereby notified that you have 30 days in which to submit a response to this notice.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

Please respond in duplicate and refer to Control Number 17295.

Sincerely,

Original Signed By
Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosure: Letter dated December 6, 1984

8512030405 851002
REG3 LIC30
21-01354-05 PDR

RIII

Mallett/cm
03/13/85

MAR 15 1985

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Radiology Department
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RIII

Mallett/cm
03/13/85

CONVERSATION RECORD

TIME 10:10A		DATE 11/7/85	
TYPE <input type="checkbox"/> VISIT <input type="checkbox"/> CONFERENCE <input checked="" type="checkbox"/> TELEPHONE			
LOCATION OF VISIT/CONFERENCE: <input type="checkbox"/> INCOMING <input type="checkbox"/> OUTGOING			
NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Dr. Chalmers		TELEPHONE NO. 946-8051	
SUBJECT CV 17295			

SUMMARY

M. Chalmers requested clarification as to what was necessary to arrange explanation from 35.2410 (* my the following letter 12/6/84) that appeared to M. Chalmers that we/AlmUI were looking for more "Qual-time experience in a radiation therapy facility" that we can either submit more info. pertaining to his therapy experience or additional request a receipt of later date if necessary experience. M. Chalmers will be sending addl. documentation of his experience in a radiation therapy facility.

ACTION REQUIRED

Info/clarification to licensee

NAME OF PERSON DOCUMENTING CONVERSATION Info/clarification to licensee		SIGNATURE [Signature]	
DATE 11/7/85			
ACTION TAKEN		SIGNATURE [Signature]	
DATE 11/7/85			
TITLE No Direct Letter offered response to 2/6/85		DATE 2/6/85	

file

AUG 02 1984

Leila Y. Post Montgomery Hospital
Radiology Department
ATTN: Donald F. Ryan
President
300 North Avenue
Battle Creek, MI 49016

Gentlemen:

Enclosed is Amendment No. 07 to your NRC License No. 21-01354-03 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive 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, Instruction and Reports to Workers; Inspection," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address.
5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.
6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

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21-01354-03 PDR

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You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

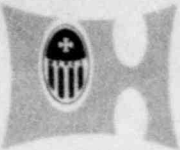
If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Materials Licensing Section

R111

Adam/as
07/30/84



Leila Hospital and Health Center

300 north avenue, battle creek, michigan 49016 telephone 616 962-8551

July 13, 1984

William J. Adam, Ph.D.
Materials Licensing Section
U.S.N.R.C.
Region III
799 Roosevelt Rd.
Glen Ellyn, IL 60137

Control No. 17534

Dear Dr. Adam:

Here is the additional information you requested.

1. The installation of the new source was complete on April 14, 1984.
2. The activity of the source was 4010 Curies on April 16, 1984.
3. The source-phantom distance (to the center of the phantom) was 81.3 cm.
4. a. The survey instrument (Keithly 36100) was a calibrated by Mr. Ohlmacher.
b. The calibration system used was a J.L. Shepherd Model 28-5, serial no. 5081. (See attached calibration certificate.) Procedures for survey instrument calibration were those submitted for our Materials License No. 21-01354-04. We have attached a copy for your convenience.
5. Electrical interlocks prohibit a Beam-On condition when the central axis of the beam is greater than 1 degree laterally and/or 5 degrees longitudinally. Further, interlocks restrict beam size and rotation combinations which would cause the beam to not be intercepted by the beam stop. All interlocks are functional.
6. The old source was transferred to Neutron Products on April 13, 1984. Their license number is MD-31-025-03. (See attached.)
7. Safety interlock testing procedures:
 - a. Room doors. The door is closed normally and observed to latch. The source is turned on. This is verified by observation of enunciator lamps on the control console, warning lamps over the room door, inside the treatment room, and on the source head, and proper operation of the "Primalert" radiation detector unit. The room door is opened sufficiently to trip the interlock switch (this is normally just slightly ajar). The source is observed to turn off by noting transition of the above conditions to a "Off" indication. With the door ajar, several attempts are made to return the source to an "On" condition. These attempts include turning the keyswitch on the console, resetting the timer, and then turning the keyswitch.

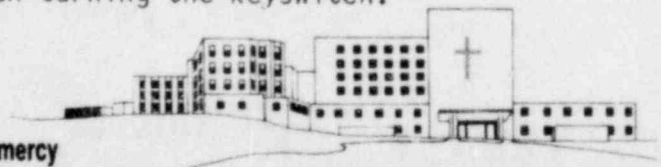
RECEIVED

JUL 19 1984

REGION III

JUL 19 1984

sponsored by the sisters of mercy

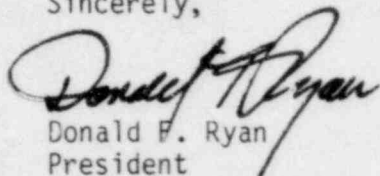


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- b. We have methods of cross-checking source condition. There is a G-M type monitor installed with a back-up nickel-cadmium power source in the treatment room. (Nuclear Associates "Primalert 10", Model 05-433.) The position of the source wheel can be seen via either the television system or the mirror system normally used for patient observation. Status of the source position lights on the source head can also be seen.
- c. Interception of the beam is determined by noting the status of the "Zone-guard" enunciator lamp on the source head. The source cannot be turned on with this lamp indicating a disallowed position.
- d. This condition is checked by attempting to turn the source on after a normal shut-off by the timer.

If you have further questions, please contact us at any time.

Sincerely,


Donald F. Ryan
President

k1/0333a

Enclosures

TELETHERAPY SOURCE TRANSFER

This is to certify that a cobalt-60 source:

Model Number: NPI-20-3800W
Serial Number: T-687
Containing 4010 curies as of 4/16/84

and which has been determined by helium pressure test and by wipe test to be leak free, has been installed in a teletherapy unit described as follows:

Manufacturer: Picker
Model Number: C9
Serial Number: 112

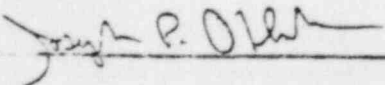
This source is hereby transferred from Neutron Products' Radioactive Materials License MD-31-025-03 to Leila Hospital and Health Center's License 21-01354-03.

This will also certify that a cobalt-60 source described as follows:

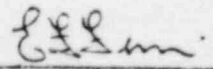
Model Number: NPI-20-3800W
Serial Number: T-390
Containing 3900 curies as of 4/1/80

has been determined by a wipe test to be leak free and has been removed from the above teletherapy unit and transferred from Leila Hospital and Health Center's License 21-01354-03 to Neutron Products' License MD-31-025-03.

We have witnessed the inspection and operation of the above teletherapy unit after completion of the installation by Neutron Products, Inc. and have found the unit to be operating properly and safely.



Date 4-13-84



Neutron Products, Inc.

Date 4-13-84

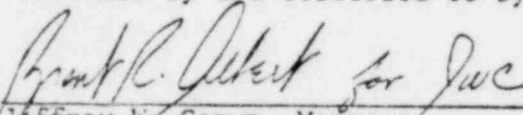
TELETHERAPY SOURCE CERTIFICATION

This certifies that the cobalt-60 source:

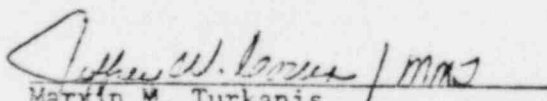
Model Number NPI-20-3800W
Serial Number: T-687
Containing 4010 curies as of 4/16/84

was fabricated by Neutron Products, Inc. in accordance with NPI specification P-4 per Drawing Number A20005 7 and was leak tested by the helium pressure test and found to be leak free on 4-3-84. The source was wipe tested and the removable activity was .042 and .0008 microcuries from the inner and outer encapsulations, respectively.

Performed by and certified to by:


Jeffrey W. Corum, Manager
Hot Cell Operations

Reviewed and approved by:


Marvin M. Turkanis
Vice President

Date 9 April 84

NEUTRON PRODUCTS inc

Necessary Information

1. Record the information describing the instrument being calibrated; include the detection medium i.e., ion chamber, scintillation crystal, or G-M tube.
2. Record the environmental conditions. Determine the air density correction factor (ADCF) due to temperature and pressure, if necessary. (See chart)
3. Determine the energy correction factor (ECF) if applicable.
4. Determine if any other correction factors are necessary (E.G. geometry). Calculate the total correction factor (CF).
5. Calculate the source calibration strength corrected for decay (E_0).
6. Calculate the source strength corrected for all factors affecting the meter reading. ($E_c = E_0/CF$)

Preliminary Checks

1. Turn the instrument on and allow to warm-up for the necessary length of time.
2. Perform the standard battery check. If the instrument fails this check, replace the batteries and repeat. If it fails again, the instrument should not be used and the electronics should be checked out.
3. Zero the instrument properly.
4. If any other checks are performed before calibration, specify and record results.

1. Measurement Set-up

Because of the high rates from the exposed source, a remote or indirect viewing system is necessary for reading the meter. The most ideal location to perform the calibration is one that:

- a) provides a high degree of shielding
- b) has a television viewing system
- c) is large enough to permit measurements as far as 18 ft. away from the source.

Presently the Co-60 room (in Therapeutic Radiology) fulfills these requirements. (Fig. 1)

The set-up employs the concrete wall, four sets of three lead bricks (approx. 4 inches thick) stacked vertically, and a TV monitor, as illustrated in Figure 2.

The calibration source in the "exposed" position emits a cone-shaped beam from the port on the side of the lead pig. The lead bricks, as illustrated, provide more than adequate shielding to the individual performing the calibration when raising the source to the "exposed" position using the gripping tongs.

No one should have any reason to be beyond the maze wall until the source drops into the "stored" position.

Calibration Measurements

1. Place the survey meter (with the chamber end-on) at a calibration point

distance (d_c) and adjust the meter until it reads the corrected calibrated exposure (E_c).

Note:

The survey meter calibration source distances, d_c , is 30 inches as shown on the tape ruler. The Cs-137 source is actually located at 1 3/8 inches more than the distance indicated on the tape ruler. This must be taken into account for the inverse-square calculation.

Record the reading after final adjustment.

2. Using the inverse-square principle, calculate the distances the survey instrument must be placed to give readings at approximately 1/3 or 2/3 of full scale for each useful scale or range.

Thus,

$$d = \text{SQRT} \frac{E_c(d_c)^2}{E_s} \text{ where } E_s \text{ is the expected exposure values.}$$

3. Place the survey meter at the calculated distances positioning the TV monitor so the meter reading can be viewed remotely. When exposing the detector to the Cs-137 beam, be sure the exposure lasts long enough for the meter to respond and reaches an equilibrium reading.

Note:

The calculated distances are measured from the source to the middle of the detector chamber. The middle of the chamber is 5.7 cm (2.24 in) from the front surface of the removal end cap.

Record the equilibrium meter reading.

Important: Rezero the instrument periodically during the measurements.

4. Calculate the percent difference, $\Delta\%$.

$$\Delta\% = \frac{E_m - E_s}{E_s} \times 100$$

5. If any readings exceed $\pm 20\%$, make the necessary adjustments to bring the instrument into calibration.

Reference Check Source Calibration

1. Perform standard battery check.
2. Zero instrument.
3. Place check source in standard geometry.

Record the reading.

4. Properly identify the check source characteristics. This is necessary to insure future reference source readings employ the same check source.

JLS SHEPHERD and Associates

740 Salem Street, Glendale, California 91203

213/245-0187

Irradiation & Calibration Equipment

Lead Shielding

Nuclear Applications

CALIBRATION CERTIFICATE

TO: Leila Y. Post Montgomery Hospital
(Victoreen)

P.O.#: 10890 Release # 7

SOURCE: 100mCi ^{137}Cs USN Type 375 Serial #F377

MOUNTING: J. L. Shepherd & Associates Model 28-5 Calibrator S.N. 5081

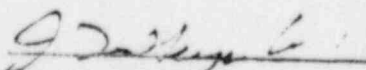
INSTRUMENT: Landsverk-64 Roentgen Meter, S.N. 438. This roentgen meter is calibrated by Dosimeters Incorporated and its calibration is directly traceable to National Bureau of Standards.

POSITION: Centered in Beam Port

DISTANCE: 60cm

OUTPUT: 64mR/hr

DATE: February 22, 1980


J. L. Shepherd

JUN 27 1984

file

Leila Y. Post Montgomery Hospital
Radiology Department
300 North Avenue
Battel Creek, MI 49016

Gentlemen:

This is in reference to a report dated April 13, 1984, signed by Joseph P. Ohlmacher, describing the results of a radiation survey of your cobalt-60 teletherapy unit. In order to complete our evaluation of the report, we need the following additional information:

1. Please submit the date of the completion of the installation of the new source.
2. With regard to your new teletherapy source, please specify the maximum number of curies.
3. With regard to the actual conditions of the survey, please specify the source-to-phantom distance used.
4. The report indicates that a Kiethly Model 36100 survey instrument was used to detect the radiation levels reported in this survey. Please:
 - A. Specify by whom these instruments were calibrated.
 - B. Describe the standards (i.e., radionuclide, activity) and procedures used to calibrate these instruments.
5. Specify the mechanical and/or electrical beam stops that are operational and restrict beam orientation when the primary beam is directed away from the integral beam absorber. Specify each direction in which the teletherapy head can be moved and the maximum angle (from vertical) of beam orientation in each direction.
6. Please submit the date the old source was transferred from the licensee as well as the name, address and license number of the recipient.
7. You have not described the tests that were conducted to ensure the proper operation of the safety interlock systems. Please describe the tests that were conducted to ensure proper operation of:
 - A. Electrical interlocks on the teletherapy treatment room doors. Your tests should be sufficient to demonstrate that the interlock system operates in accordance with the requirements of Condition 17. of your license.

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- B. Teletherapy source "on-off" indicators, electrical and mechanical, both at the source housing and at the teletherapy machine control panel. You should use a method of cross-checking these indicators, such as using a radiation detection instrument, to ensure that the indicators correspond to the actual condition of the source.
- C. Electrical and/or mechanical stops installed for the purpose of limiting use of the primary beam of radiation. Your tests should be sufficient to show that the stops limit use of the primary beam in the manner described in survey report.
- D. Teletherapy treatment timing device. In addition to demonstrating timer accuracy, your tests should be sufficient to show that the source returns to the "off" position at the end of the preset time and that the source will not return to the "on" position until the timer is reset.

Please submit the above information in duplicate within thirty (30) days so that we may complete our evaluation of your report. Your response should reference Control No. 17534.

Sincerely,

William J. Adam, Ph.D.
Materials Licensing Section

RIII

Adam/bm
06/25/84

Radiation Safety Survey
April 13, 1984

Date: 5/30/84
Log: May 28/84
By: [Signature]
Orig. To: [Signature]
Action Compl: [Signature]

Reason for survey: Replacement of Cobalt-60 source

Global survey conditions: Open field beam of 35 x 35 cm set
Approximately cubical scatterer consisting of
25 cm acrylic plastic (SCRAD phantom) set with
its center on the central ray at the isocenter.

Survey Instrument: Keithly 36100 Survey Meter, Serial No. 11945
Date of last calibration: Dec. 14, 1983

Location	Gantry Angle			
	0 deg	90 deg	180 deg	270 deg
1. Roof over therapy unit (at ~1 meter above roof and *=>contact)	0.1 mR/hr ~0.1 *	0.1 mR/hr 0.2 *	1.7 mR/hr 2.5 *	0.1 mR/hr 0.2 *
2. East wall of unit (at ~1 meter from wall and *=>contact)	0.1 0.1 *	1.0 1.6 *	0.1 0.2 *	0.1 0.1 *
3. West wall of unit (at ~1 meter from wall and *=>contact)	<0.1 <0.1 *	<0.1 <0.1 *	0.1 0.1 *	<0.1 2.8 **
4. South wall of unit (at ~1 meter from wall and *=>contact)	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1
5. North wall in office (at ~1 meter from wall and *=>cont.)	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1
6. Crawl space under unit. Field in ante space to south of unit.	0.1	<0.1	<0.1	<0.1
7. Crawl space under unit. Field under unit.	2.3	<0.1	<0.1	<0.1

** This dose rate was seen at approximately 2 meters above the floor in the control area. Fields at normal occupancy elevations were ~0.1 mR/hr or less.

Comments: The crawl space under the unit is a restricted access area. There are warning lights to indicate source-on condition, and the sole entrance is properly posted. The roof over the unit has been made a restricted area. Posting was placed at the entrance door from the third level. The hospital engineer was advised and will contact the therapy department should access to either area be required.

Joseph P. Ohlmacher
Joseph P. Ohlmacher

Free Survey
FEE EXEMPT

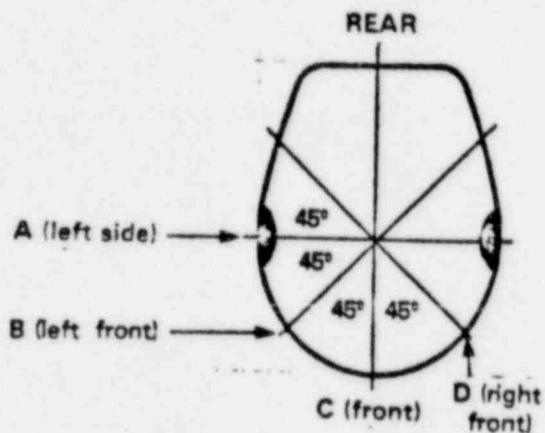
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Figure F-1 TELETHERAPY HEAD SURVEY

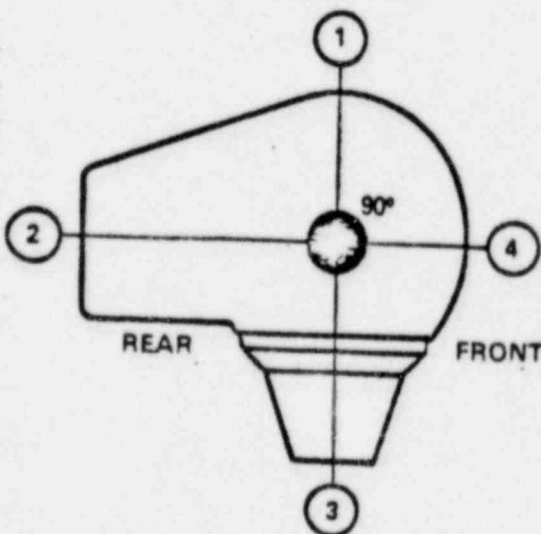
(Source in "OFF" position.
Measurements taken one meter
from source)

Top View-Showing
orientation
of Views A through D

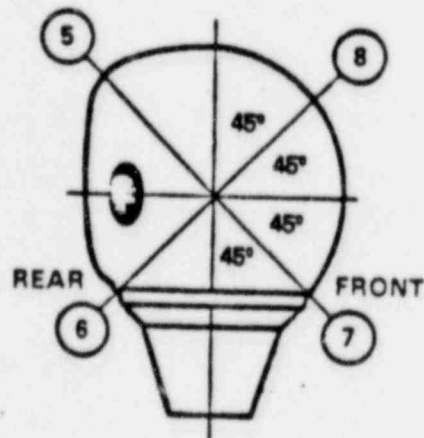
Position No.	Radiation Level (mr/hr)
View A	
1	2.3
2	0.4
3	2.7
4	1.0
View B	
5	1.7
6	1.2
7	0.5
8	0.7
View C	
9	0.6
10	0.8
View D	
11	0.7
12	1.3
13	1.7
14	1.2
Average value	1.2
Maximum value	2.7



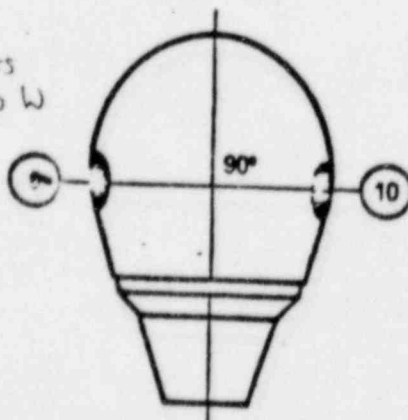
View A-Vertical
from left side



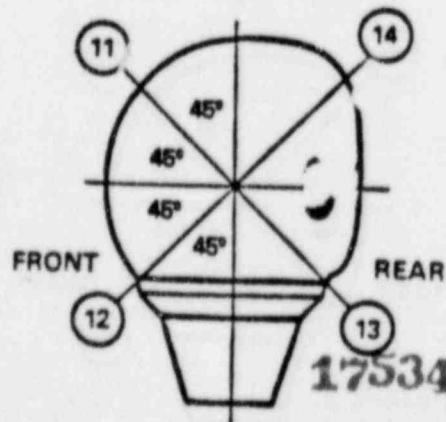
View B-Vertical
from left front



View C-Vertical
from front



View D-Vertical
from right front



Date of survey 4-13-84
Instrument used KEITHLEY 36100

Manufacturer's name & model number of teletherapy source NEUTRON PROBE NPE-20-3800 W

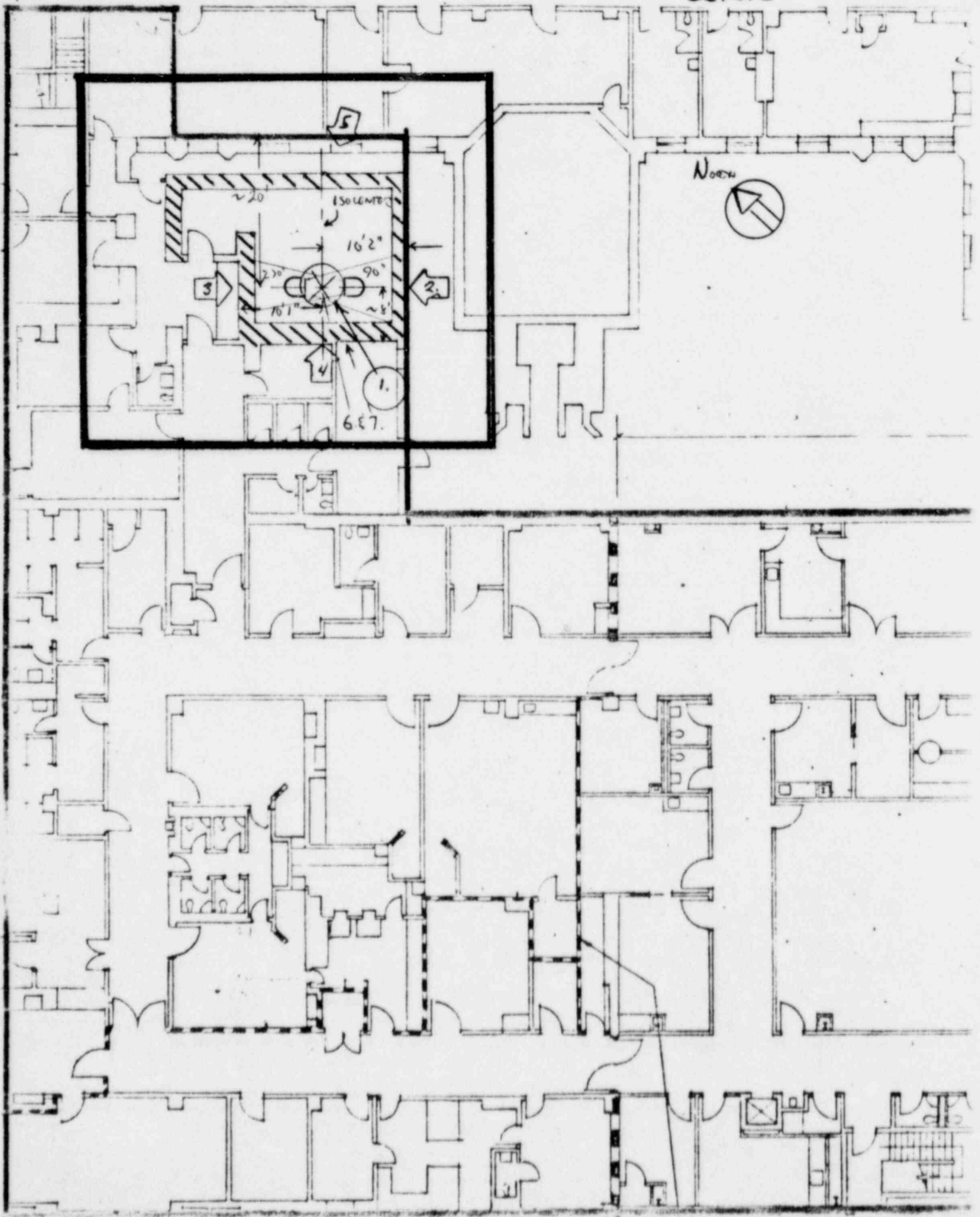
Date of installation 4-13-84

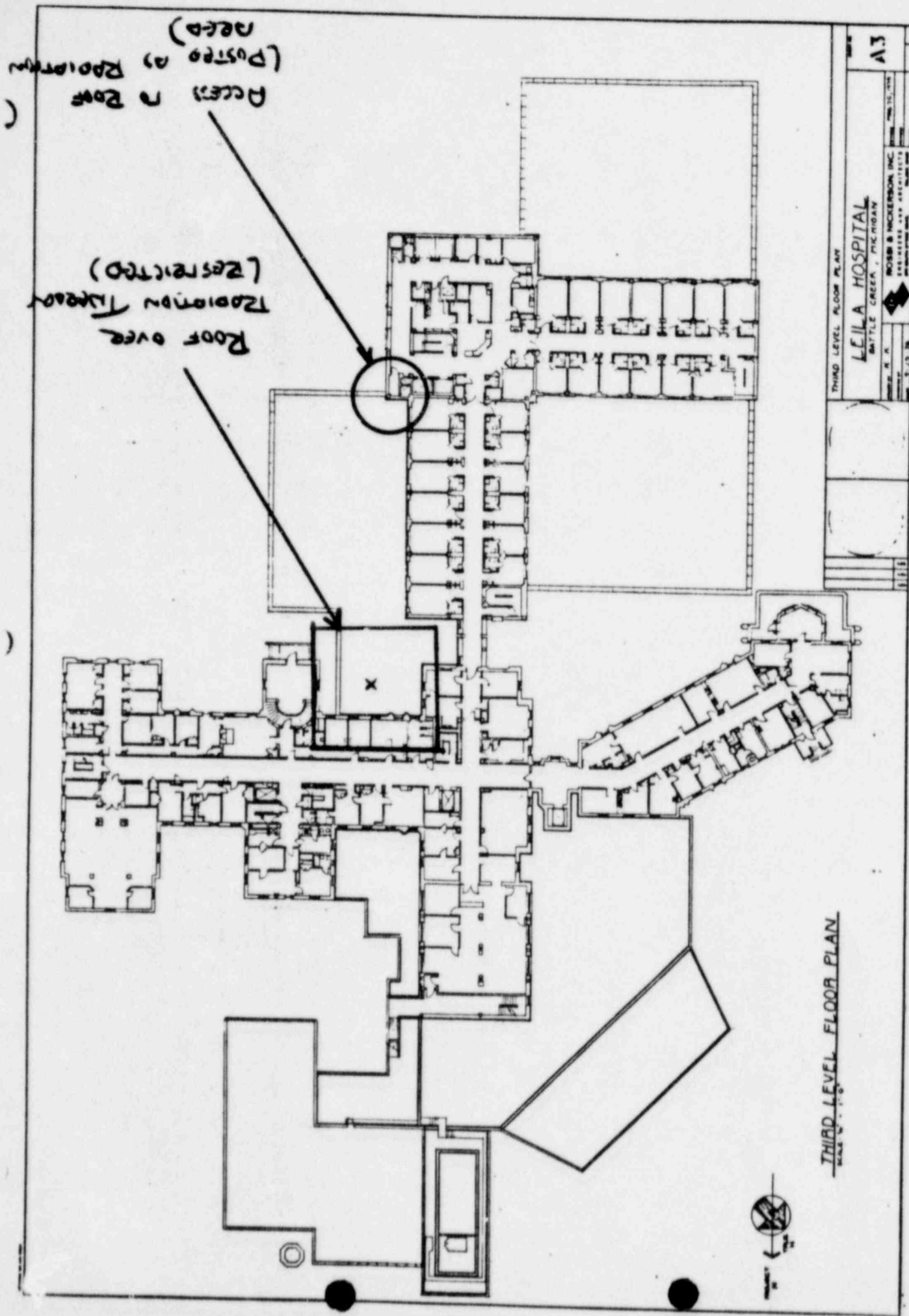
OUTPUT 4479 ☒ RHM
☐ RMM

Date of output measurement 4-13-84

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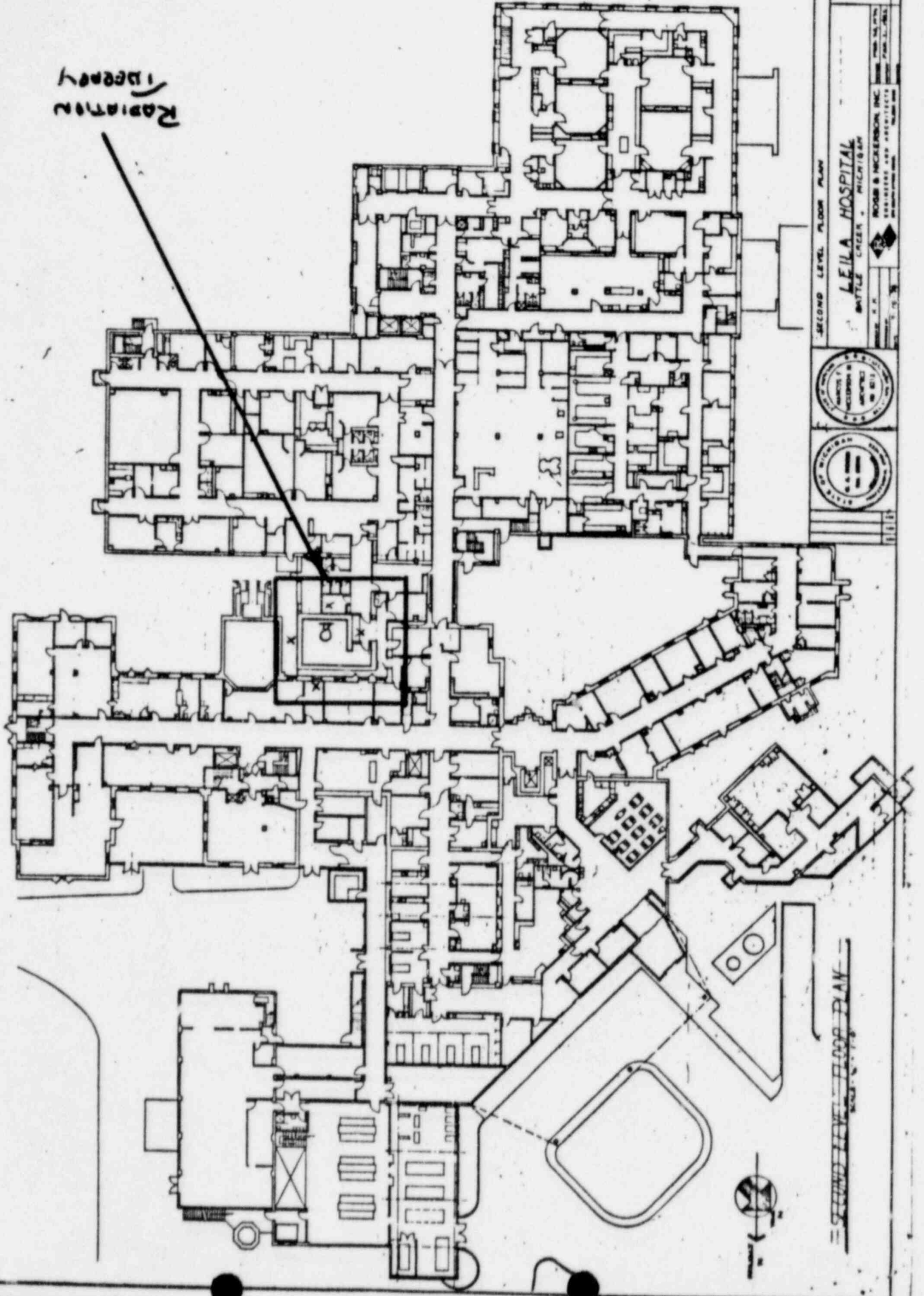
RADIATION THERAPY
DETAIL





17534

RADIATION
IDENTIFY



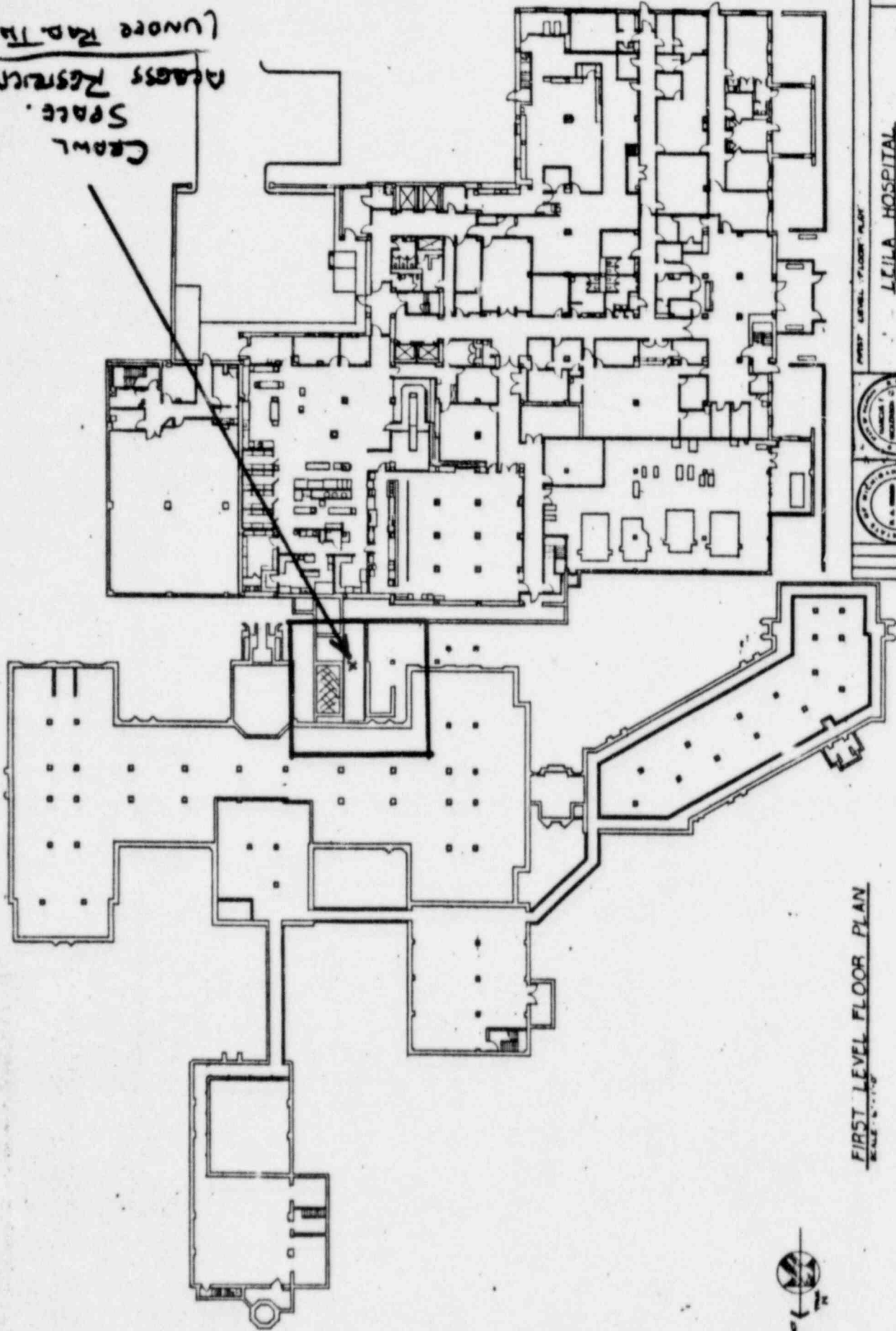
SECOND LEVEL FLOOR PLAN
LEILA HOSPITAL
BATTLE CREEK, MICHIGAN
ROOS & NICKERSON, INC.
REGISTERED ARCHITECTS
BATTLE CREEK, MICHIGAN



SECOND LEVEL FLOOR PLAN

17534

CEASE
SPACE
ACCESS RESTRICTED
(UNOPE ROAD TH.)



FIRST LEVEL FLOOR PLAN



LEILA HOSPITAL
BATTLE CREEK, MICHIGAN
ROUSE & NICKERSON, INC.
DESIGNERS AND ARCHITECTS