FORM NRC-313M (3-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Harper-Grace Hospitals, Harper Division
Radiation Oncology Department
3990 John R.
Detroit, Michigan 48201
TELEPHONE NO.: AREA CODE (313) 494 - 8111

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

2. PERSON TO CONTACT REGARDING THIS APPLICATION

William G. VandeRiet, Ph.D.
TELEPHONE NO.: AREA CODE (313) 494 - 4285

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

(See Attachment 4)

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

William G. VandeRiet, Ph.D.
(See Attachment 4)

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Atomic Energy of Canada Cobalt-60 source model C-146 or C-151. Two sources of not more than 12,000 curies each (200 RMM each) to be used in an A.E.C.L. Cobalt-60 teletherapy unit Model 780.			

8008130622

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and see attachment 4
X	Supplement A Attached for RSO. see attachment 4
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
N.A.	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached see attachment 13

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
N.A.	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
N.A.	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
N.A.	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
N.A.	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. and Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

N.A.

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY: 7A

(2) LICENSE FEE ENCLOSED: $ 300.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Thomas Feurig

(1) NAME *(Type or Print)* Thomas Feurig

(2) TITLE Administrator

c. DATE

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August 4, 1980

ITEM 4

Users for Human Use

1. B. Considine, Jr., M.D.
   (21-04127-06)

2. Gangadhar V. Vaishampayan, M.D.
   (21-04127-06)

3. Karan S. Dosi, M.D.
   (21-04127-06)

4. James G. Gamero, M.D.
   (21-04127-06)

5. William E. Powers, M.D.
   (21-04127-06)

6. H. Gunter Seydel, M.D.
   (21-04127-06)

7. Jeannie Jones Kinzie, M.D.
   American Board of Radiology
   Therapeutic Radiology - 1972

For Calibration and Testing

1. William G. VandeRiet, Ph.D.
   American Board of Radiology
   Radiological Physics - 1973
   (21-04127-06)

2. Francis J. Connolly, Ph.D.
   American Board of Radiology
   Therapeutic Radiological Physics - 1979
   (21-04127-06)

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ITEM 7

MEDICAL ISOTOPE COMMITTEE

Burt T. Weyhing, M.D., Chairman	Radiologist - Nuclear Medicine
Jaroslaw Muz, M.D.	Radiologist - Nuclear Medicine
Thomas M. Kumpuris, M.S.	Nuclear Medicine Physicist
William G. VandeRiet, Ph.D.	Radiation Therapy Physicist
Raymond Bauer, M.D.	Internist
George Fischer, Ph.D.	Clinical Chemist
Subhash Gulati, M.D.	Internist
John Schneider, M.D.	Internist
Rodman Taber, M.D.	Surgery
Kenneth Bergsman, M.D.	Oncology
Basil Considine, Jr., M.D.	Radiation Oncologist
Thomas Feurig	Administration
John Kim, Ph.D.	Diagnostic Radiological Physicist

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ITEM 9

1. Victoreen Model 491 G.M. survey meter with Model 491-30 tube.

2. Victoreen Model 470 Panoramic ionization survey meter.

3. Area Monitor: Nuclear Associates "Primalert 35"

4. Calibration of output: Keithley 616 electrometer with Nuclear Enterprises Balwin - Farmer 0.6cc ionization chamber. System calibrated at Victoreen Regional Calibration Laboratory in January, 1980.

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ITEM 11

FACILITIES AND EQUIPMENT

The proposed Cobalt-60 unit will be located in treatment room 6 of Harper Hospital's Radiation Oncology Center as shown in Figure 1. This facility is completely underground with a landscaped mall above the facility. There is no occupiable space below the treatment room. The south and east walls are outside walls with 40 feet or more of earth between them and the nearest occupiable buildings. The walls and ceilings of the treatment rooms have been constructed with concrete having a density of 147 pounds per cubic foot. The entrance door to the teletherapy room has a 3/8 inch lead liner. Duct work for heating and air conditioning has been brought in above the entrance door and behind the maze wall at a height of at least seven feet. Some of the plumbing and electrical conduits have been brought in through the north wall at a depth of at least 20 inches below the finished floor level. The teletherapy room will contain two cameras to provide different views and backup monitoring. In the event that both cameras or the monitor fails, patient treatment will be ceased until monitoring is restored. Two-way audio communication will be provided by an intercom system. The entrance door to the teletherapy room is equipped with two switches wired in series to shut the unit "off" if the door is opened during an "on" condition. A red light over the door will indicate the "on" condition. The room will be equipped with an area monitor.

The Cobalt-60 teletherapy unit to be installed is a rotational Atomic Energy of Canada Model 780. The maximum source loading for this unit is 200 RMM (approximately 12,000 curies). The workload assumed in this evaluation is 6.4×10^7 mR/week at one meter for a patinet load of approximately 50 patients per day at 80 cm treatment distance. Head leakage of 0.1% of the primary at 1 meter has been utilized. The tenth-value-layers and scatter factors used in this analysis were taken from NCRP Report No. 49 and are reproduced in Table I. Since this room was designed for photons up to 10MV, the analysis of weekly exposure levels has not included any use factors for beam orientation but are based upon the "worst case" condition for each location considered. This unit will not have a primary beam stopper.

The estimated radiation levels that are anticipated in areas around the installation are presented in Table II. The locations considered are shown in Figures 2, 3, and 4. The weekly exposure values were calculated using the formula:

$$\frac{\text{mR}}{\text{week}} = \sum \frac{W \times Fi \times Si \times 10^{-x/TVL}}{d^2}$$

W = workload at one meter
Fi = fractional scatter for beam orientation i
Si = leakage factor
d = distance in meters

The summation is to add leakage and scatter together for secondary barriers under the "worst case" condition. The radiation levels presented in Table II demonstrate that the radiation levels adjacent to this proposed teletherapy installation do not exceed 10 mR/week.

TABLE I

NCRP 49 Co-60 Parameters

Source	TVL*	Scatter Factor**
Primary	20.6	
Leakage	20.6	0.001
30 degree scat.	20.3	0.0060
45 degree scat.	19.8	0.0036
60 degree scat.	19.2	0.0023
90 degree scat.	15.4	0.0009

* cm concrete 147 lbs./ft^3
** for 400 cm^2 field

TABLE II

Location	mR/week Primary	Secondary	Max* mR/hr.
1.	0.003	--	.0005
2.	0.003	--	.0005
3.**	--	--	--
4.	--	.01	.002
5.	--	.0004	.0001
6.	--	--	--

* 200 RMM
** used earth to concrete ratio of 1.57:1 based upon density ratios as per NCRP No. 49 (TVL = 33 cm)

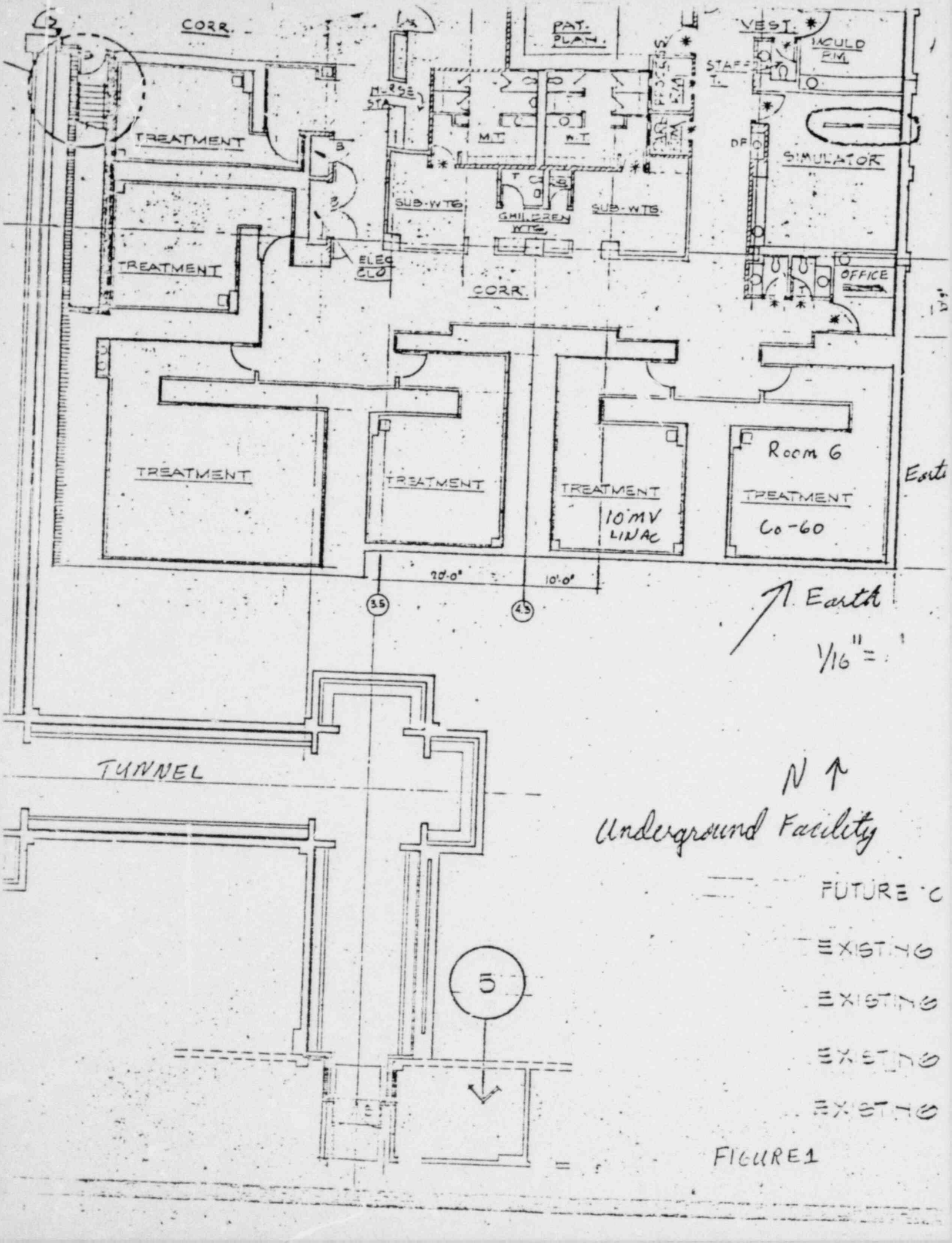

CORR.
PAT. PLAN.
VEST.
INCUD FIN.
STAFF L.
NURSE STA.
M.T.
M.T.
SIMULATOR
SUB-WTG.
CHILDREN WTG.
SUB-WTG.
OFFICE
ELEC CLO
CORR.
TREATMENT
TREATMENT
TREATMENT
TREATMENT
TREATMENT
10 MV LINAC
Room 6
TREATMENT
Co-60
20'-0"
10'-0"
3.5
4.3
Earth
1/16" =
TUNNEL
N
Underground Facility
FUTURE
EXISTING
EXISTING
EXISTING
EXISTING
5

FIGURE 1

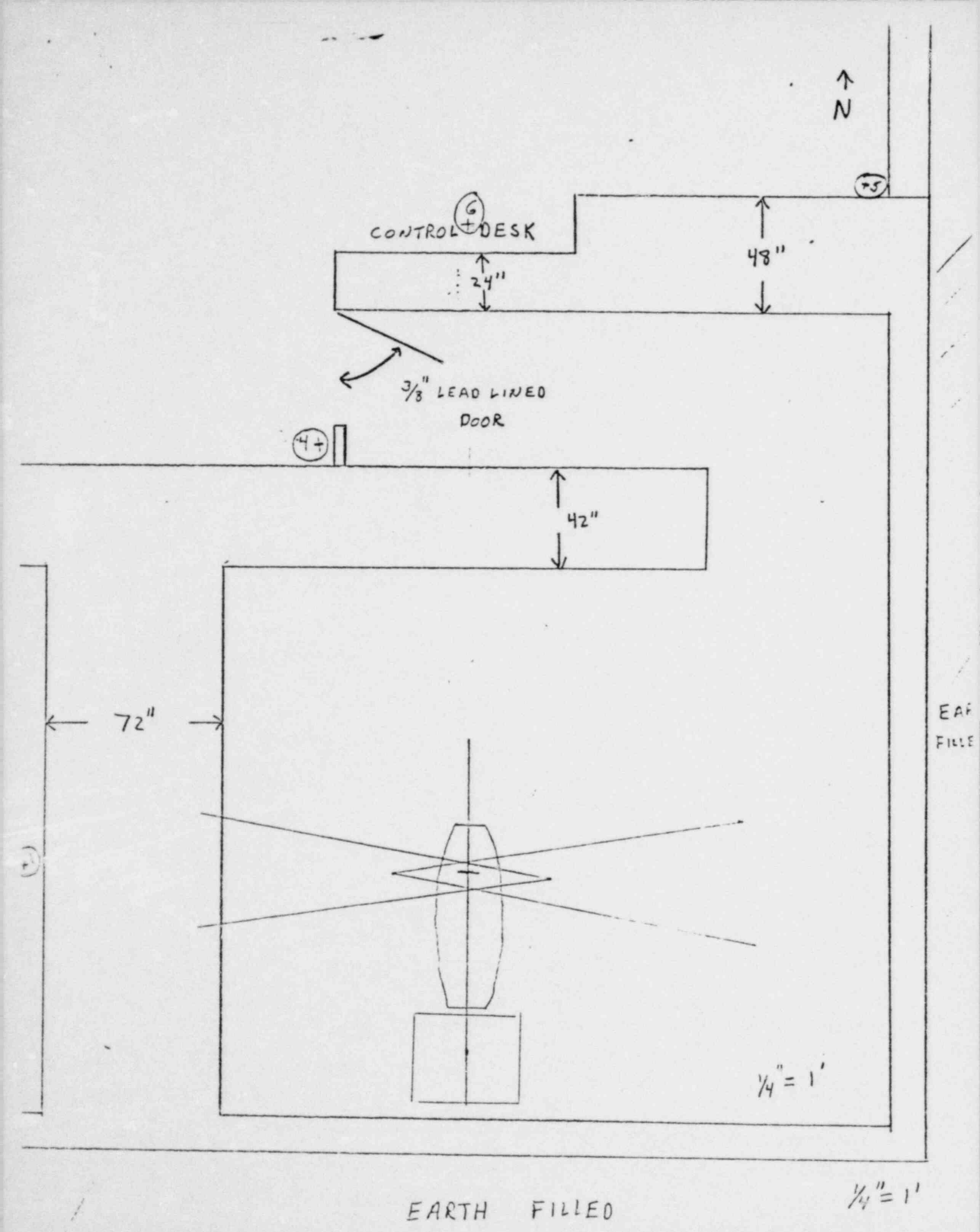
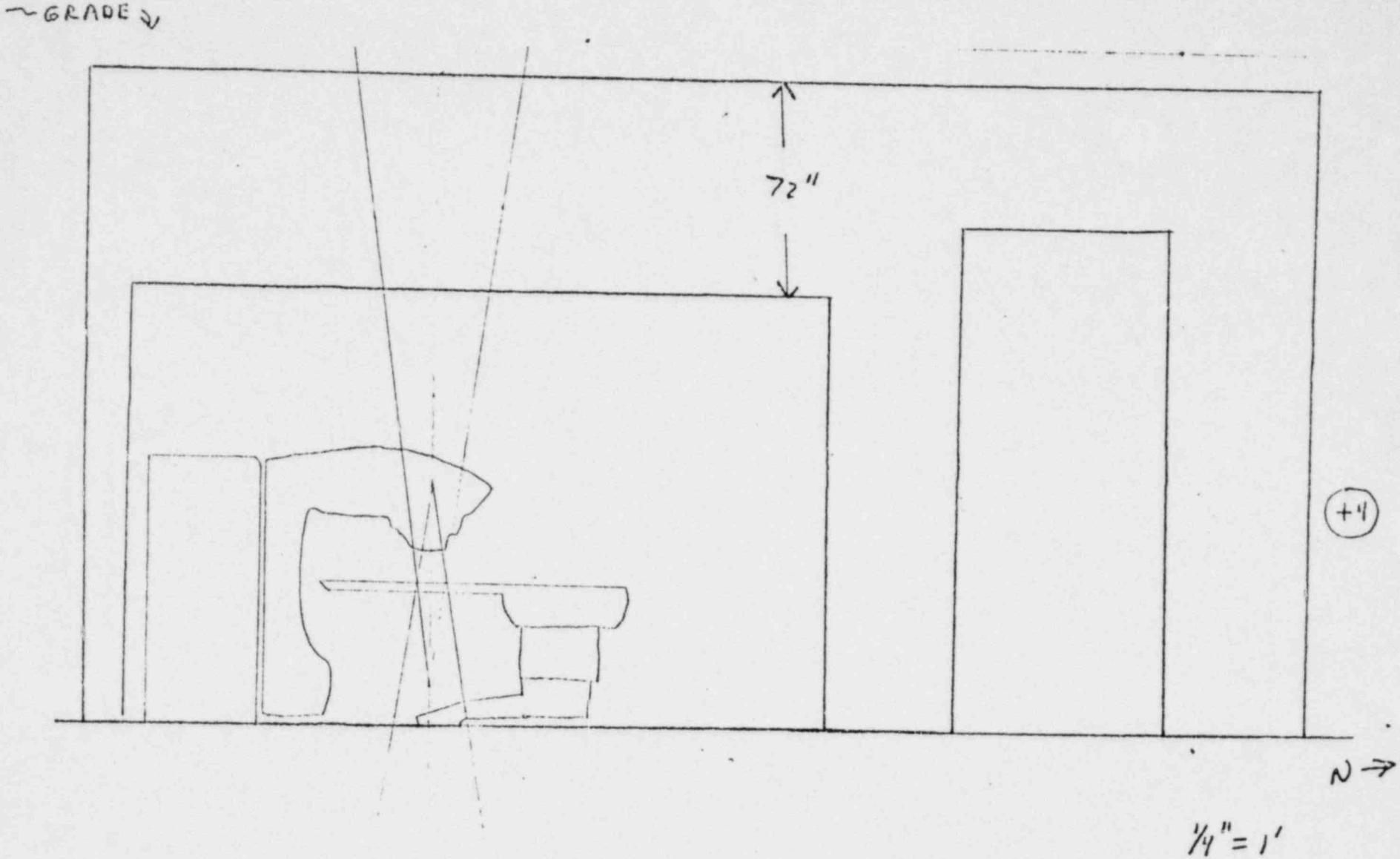

N
CONTROL DESK
24"
48"
3/8" LEAD LINED DOOR
42"
72"
1/4" = 1'
EARTH FILLED
1/4" = 1'

FIGURE 2



1/4" = 1'

FIGURE 3

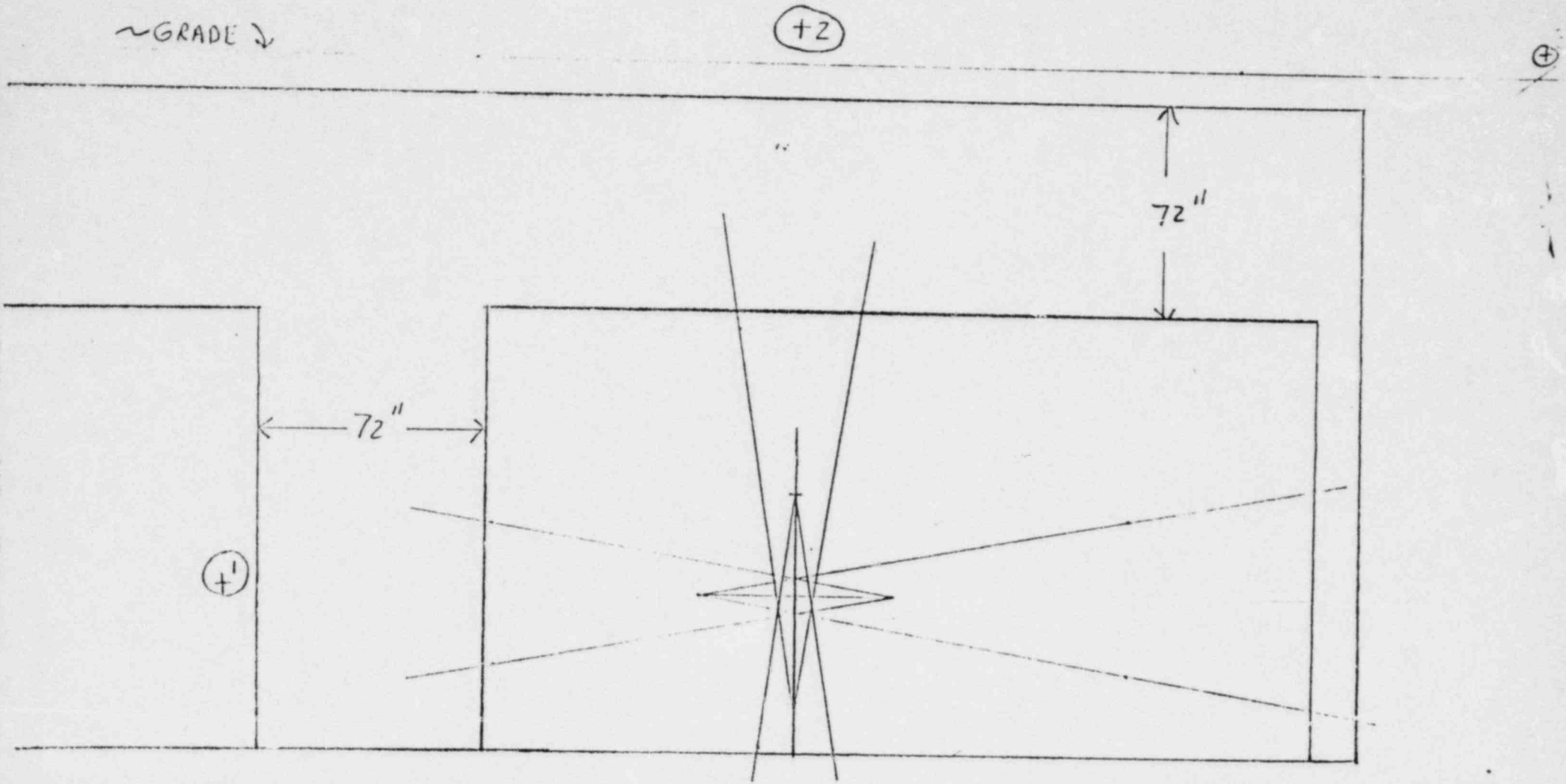


FIGURE 4

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ITEM 12

Technologists:

Only certified radiation therapy technologists or radiologic technologists from an approved training program will be accepted as radiation oncology staff to operate the teletherapy unit under the supervision of one of the approved users. Radiologic technologists who have not received additional training in radiation oncology will receive on the job training by our current staff of certified radiation therapy technologists, radiation physicists, and radiation oncologists.

Our current staff of technologists have all had experience under license no. 21-04127-06.

Others:

Ancillary personnel such as nurses, medical students, etc. who would have any contact with the teletherapy unit shall be under the supervision of the radiation oncologists or the chief radiation technologists and shall be instructed in accordance to the level or their involvement primarily through on-the-job training.

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ITEMS 13 & 14

Source changes, inspections, and servicing of the teletherapy source drive mechanism will only be performed by individuals licenced by the N.R.C. or an agreement state.

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ITEM 16

EMERGENCY PROCEDURES - TELETHERAPY TREATMENT ROOM

A. LOSS OF PATIENT VIEWING: If equipment failure results in a loss of patient viewing, terminate the treatment and record the treatment time. Do not resume patient treatments until the patient viewing devices have been restored to normal operation.

B. EQUIPMENT FAILURE RESULTING IN THE SOURCE REMAINING "ON"

CAUTION: STAY OUT OF THE DIRECT BEAM AT ALL TIMES

1. Ambulatory patient:
   (a) Instruct the patient to get off the treatment couch and leave the room.
   (b) Record the estimated treatment time.
   (c) Close and post the treatment room door and secure the room against unauthorized entry.
   (d) Notify the responsible individuals below.

2. Non-ambulatory patient:
   (a) If possible, direct the primary beam away from the patient using the controls at the console.
   (b) Enter the treatment room and rotate the treatment couch away from the primary beam.
   (c) Remove the patient from the room.
   (d) Record the estimated treatment time.
   (e) Close and post the treatment room door and secure the room against unauthorized entry.
   (f) Notify the responsible individuals below.

C. EMERGENCY TELEPHONE NUMBERS:

William G. VandeRiet, Ph.D.
Office: 494-4285
Home: 435-0625

Francis J. Connolly, Ph.D.
Office: 494-4285
Home: 478-9183

John Kim, Ph.D.
Office: 494-8068
Home: 881-5372

Tom Kumpuris, M.S.
Office: 494-8417

A.E.C.L.
Chicago Office: 312-593-3242

D. MANUAL SOURCE TURN "OFF"

1. Take the red "T" rod kept at control console and enter the treatment room.

2. Insert "T" rod into the hole in the white front head trim cover and push the source into the "off" position.

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ITEM 17

Area surveys will be conducted by William G. VandeRiet, Ph.D. and/or by Francis J. Connolly, Ph.D. in accordance with criteria presented in the NRC document titled "Draft Licensing Guide for Teletherapy Programs".

Leak testing will be performed by either of the individuals mentioned above. The procedure will consist of wiping the inside of the adjustable and primary collimators which are accessible when the source is in the "off" position. The wipes will be counted in a NaI well-type scintillation counter and compared to a small calibrated Co-60 standard. Minimum detectable activity (MDA) will be defined as counts exceeding the background count by 3 times the standard deviation of the background count. The leak test report and results will demonstrate that the system is capable of detecting an MDA of less than 0.05 microcuries of Co-60.

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ITEM 18

Removal of Co-60 teletherapy sources will only be performed by individuals licenced by the NRC or an agreement state to do so.

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ITEM 23

The teletherapy unit will be used for the treatment of humans by or under the supervision of the individual users listed in item 4.