

MATERIALS LICENSE

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 transport 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.

Licensee		301784
1. Cleveland Clinic Foundation Radiation Safety Office, W-18	3. License Number	34-00466-05
2. 9500 Euclid Avenue Cleveland, OH 44195-5199	4. Expiration Date	November 30, 2001
	5. Docket or Reference No.	030-34234
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. Cobalt-60	A. Sealed sources (General Electric Co. AB Elekta Model No. 43047)	A. 6600 curies (201 sources not to exceed 36 curies each)

9. Authorized Use:

- A. For installation, operational testing, calibration, and storage only in a Leksell Gamma System Model 23004 Type B (a.k.a. Gamma Knife or Gamma Stereotactic Radiosurgery Unit).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at the Northern Ohio Gamma Knife Center at the Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio.
11. License material shall be used (limited to Subitem 9.A.) and stored under the supervision of Xiaowei Zhu, Martin Weinhaus, Ph.D., or Twyla Willoughby.
12. The Radiation Safety Officer for this license is Xiaowei Zhu.
13. A. The Gamma Knife shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate or registration referred to in 10 CFR 32.210.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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- C. The test sample shall be taken from selected accessible surfaces of the Gamma Knife. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used helmets. A minimum of a single wipe of the entire surface of the collimator will taken.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results and corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission and or an Agreement State of perform such services.
14. A. Access to the Gamma Knife room shall be controlled by a door at each entrance. Such doors shall be normally closed.
- B. Each entrance to the Gamma Knife room shall be equipped with an electrical interlock system that will remove the patient from the focus beam of radiation upon opening of any entrance door. The interlock system shall be connected in such a manner that the patient cannot be returned to the focus beam until all treatment room entrance doors are closed and the control is reset at the control panel.
- C. Electrical interlocks on entrance doors to the Gamma Knife room shall be tested for proper operation at least once every 6 months. Records of test results shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. In the event of malfunction of any door interlock, the Gamma Knife control shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

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15. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the Gamma Knife unit that could result in increased radiation levels in areas outside the Gamma Knife treatment room shall be evaluated by a radiation survey made in accordance with Condition 16. and reported to the Commission within 30 days following completion of the change(s).
- B. Relocation of the Gamma Knife unit to a new facility is not permitted without prior approval of the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 19. and reported to the Commission within 30 days after completion of the move.
16. Before initiation of a treatment program, and subsequent to each installation of a Gamma Knife source, radiation surveys and tests shall be performed in accordance with the following:
- A. A radiation survey shall be made of:
- (i) The Gamma Knife source housing, with the shielding door closed. The maximum and average radiation levels at 1 meter from the Gamma Knife housing in the closed position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.
 - (ii) All areas adjacent to the treatment room with the Gamma Knife shielding door in the open position. The survey shall be performed with a phantom in the focus beam of radiation and shall clearly establish:
 - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.1201 of 10 CFR Part 20.
 - (b) The quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301 of 10 CFR Part 20.
- B. Tests shall be made to determine proper operation of:
- (i) Electrical interlocks on entrance doors to the Gamma Knife treatment room.
 - (ii) The Gamma Knife treatment timing device.
- C. A report of the results of the above surveys and tests shall be sent to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Materials Licensing Branch not more than 30 days after each installation of a Gamma Knife source.

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17. The following shall be performed by the manufacturer or persons specifically licensed by the Commission or an Agreement State to perform such services:
 - A. Installation, relocation, or removal of Gamma Knife units containing sources.
 - B. Source exchange.
 - C. Any maintenance or repair operations on the Gamma Knife unit involving a mechanism that could expose the source, reduce the shielding around the sources, or compromise the safety of the unit and result in increased radiation levels.
18. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source change only. This exemption is granted for no more than 30 days for any one source change.
19. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The 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 August 21, 1996; and
 - B. Letters dated October 9, 1996 and November 7, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

November 13, 1996

By

Patricia J. Alene
Materials Licensing Branch, Region III

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(FOR LFMS USE)
 INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
 and
 Regional Licensing Sections

Program Code: _____
 Status Code: 3 _____
 Fee Category: _____
 Exp. Date: 0 _____
 Fee Comments: _____
 Decom Fin Assur Req'd: _____
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LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: CLEVELAND CLINIC FOUNDATION
 Received Date: 960828
 Docket No: 3034234
 Control No.: 301784
 License No.: _____
 Action Type: New License

2. FEE ATTACHED

Amount: 2800
 Check No.: 475965

3. COMMENTS

Signed _____
 Date _____

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

1. Fee Category and Amount: 7A \$2800

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

Amendment _____
 Renewal _____
 License ☒ _____

3. OTHER _____

Signed _____
 Date _____

Log	SC Aug 15 2001
Remitter	
Check No.	475965
Amount	\$2800
Fee Category	7A
Type of Fee	App
Date Check Rec'd	8/29/96
Date Completed	9/4/96
By:	SC

SEP 09 1996

1996 SEP - 3 AM 11:11

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)



A. NEW LICENSE



B. AMENDMENT TO LICENSE NUMBER _____



C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

The Cleveland Clinic Foundation
Radiation Safety Office, W-18
9500 Euclid Avenue
Cleveland, Ohio 44195-5199

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195
(The Northern Ohio Gamma Knife Center)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Judy A. McKenna, MS

TELEPHONE NUMBER

216-444-6645

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7.A. AMOUNT ENCLOSED \$ 2,800.00
13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 82 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Melinda L. Estes, MD, Associate Chief of Staff

SIGNATURE

DATE

8-21-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		RECEIVED AUG 28 1996 301784
APPROVED BY				DATE	

pm: 8-27-96

REGION III



THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

Mr. Kevin Null
Nuclear Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Radiation Safety / QQ10
216/444-6645

August 23, 1996

New License Application
Delivery Date scheduled: 11/1/96

Dear Mr. Null:

As we have discussed, attached is a new license application for The Cleveland Clinic Foundation (CCF) for a Leksell Gamma System Model 23004 Type B. Contractual arrangements with the manufacturer/distributor identify a delivery date of November 1, 1996. From prior discussions, you had indicated 60 days for the review of a new license application should be adequate. Please contact me at (216) 444-6645 for any further information needed to assist in the issuance of this license by November 1, 1996. This application was compiled following guidance in the DRAFT Gamma Stereotactic Radiosurgery Module and a Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs.

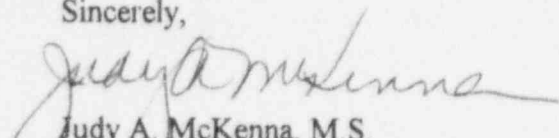
This unit will be housed in a new building on CCF property intended for the development of the Northern Ohio Gamma Knife Center. The unit will be owned and operated by CCF.

A few procedures do not have complete details as the operating manual for the equipment is routinely not distributed until the unit is delivered. Upon receipt, appropriate sections will be incorporated into our draft procedures. In addition, exposure rate values for the emergency section will be incorporated following performance of surveys required by 10 CFR 35.641.

From conversations with Elekta personnel, I understand the NRC's Dallas office has observed a loading of a Type B Gamma Knife in the event questions arise with our proposed procedures.

Your timely attention to this license application is most appreciated.

Sincerely,


Judy A. McKenna, M.S.
Director, Radiation Safety

RECEIVED

AUG 28 1996

REGION III

Item 5 - Radioactive Material

5.1 Sealed sources to be used in teletherapy units:

1. Radionuclide: Cobalt-60 (Co-60)
2. Manufacturer's name & model number:
Manufacturer/distributor: Elekta Instrument, Inc. (distributor)
Elekta Instrument SA (manufacturer)
Sealed Source Model designation: General Electric Company
AM Elekta Model No. 43047
3. Maximum amount of radioactive material in any one source:
No single source to exceed 36 Curies, with a mean average not to exceed 32.83 Curies. A total of 201 sources will be housed in a Leksell Gamma System Model 23004 Type B.
Maximum activity total: 6600 Curies
4. Maximum output for a source containing the maximum amount of radioactive material: The radiation dose rate from the 201 sources at the focal point at the time of loading is > 3 Gy/min and < 4 Gy/min.
5. Total amount of radioactive material to be possessed at any one time:
6600 Curies except during reloading then activity will be less than 13,200 Curies, with one set of 201 sources in a transport container.

5.2 Teletherapy Unit

- Manufacturer/distributor: Elekta Instruments, Inc. (distributor)
Elekta Instruments, SA (manufacturer)
Model: Leksell Gamma System Model 23004 Type B

Item 6 - Purpose for which licensed material will be used.

This unit will be utilized for:

1. human use
2. the irradiation of cells, tissues and animals in accordance with research protocols.

Item 7 - Individuals responsible for Radiation Safety Program and their Training Experience.

Proposed Authorized Users -- Human Use

Attachment 1 contains the required Supplement A forms for the following physicians:

Roger M. Macklis, M.D.
John H. Suh, M.D.
Jay P. Ciezki, M.D.

Item 7 (cont.)

Proposed Authorized Users -- Nonhuman Use

Attachment 2 contains the required Supplement A forms for the following individuals:

Roger M. Macklis, M.D.
John H. Suh, M.D.
Jay P. Ciezki, M.D.
Martin S. Weinhaus, Ph.D.
F. Christopher Deibel, Jr., Ph.D.

Proposed Radiation Safety Officer

Attachment 3 contains the required Supplement A for Ms. Judy A. McKenna, M.S., DABR., the present RSO for NRC License 34-00466-01.

Proposed Gamma Stereotactic Radiosurgery (GSR) Physicist

Attachment 4 contains the required Supplement A for the proposed GSR physicists:

Martin S. Weinhaus, Ph.D.
F. Christopher Deibel, Jr., Ph.D.

Item 8 - Training for Individuals working in or frequenting Restricted Areas

8.1. Training program

8.1.1 Training Program for Individuals responsible for GSR Treatment of Patients

The "team" for the GSR program will include the GSR physicist, neurosurgeon, radiation oncologist, radiation therapist and/or dosimetrist, nurse as needed and anesthesiology support as needed. A qualified neurosurgeon or radiation oncologist will see the patient as the intake physician and determine if the case seems reasonable for radiosurgery. If so, the case will be presented at a radiosurgery conference, and both a qualified neurosurgeon and a qualified radiation oncologist must agree that the case is appropriate before the patient is scheduled. Both the neurosurgeon and the radiation oncologist will discuss risks and obtain informed consent for the overall procedure with each emphasizing the issues most germane to their specialty. The neurosurgeon is responsible for the application and removal of the stereotactic head frame, determines the lesion boundaries and confirms the appropriateness of the overall treatment plan. The radiation oncologist prescribes the appropriate radiation doses on the written directive and the qualified radiosurgery physicist is responsible for overseeing the delivery of the prescription and quality assurance aspects of treatments. Each plan will be signed by both physicians and the physicist prior to implementation. At least one of the qualified physicians will be physically present at all times during the actual procedure. For unstable cases (as judged by the team), both the neurosurgeon and radiation oncologist will be present. The therapist monitors the patient and equipment controls during treatment and assists with patient positioning.

Item 8.1.1 (cont).

Neurosurgeons: Gene H. Barnett, M.D.
 David W. Miller, M.D.

Radiation Oncologists: Roger M. Macklis, M.D.
 John H. Suh, M.D.
 Jay P. Ciezki, M.D.

Radiosurgery Physicists: Martin S. Weinhaus, Ph.D.
 F. Christopher Deibel, Jr., Ph.D.
 Twyla Willoughby, M.S.

Therapists: Mary DeVito, RTT
 Pam Saffle, RTT
 Kelly Kardos, RTT
 Ellen Stevens, RTT
 Michael Davis, RTT

Dosimetrists: Dave Abraham, RTT, CMD
 Carole Belfi, RTT, CMD
 Mark Murray, RTT, CMD
 Lynn Vukich, RTT, CMD

Nurse: Joan Wendel, RN, MSN, OCN
 Arlene White, RN
 Jeannie Hamker, RN
 Laura Laufman, RN

The neurosurgeons, radiation oncologists and physicists will receive instruction in the technical operation and maintenance of the unit. In addition to these individuals, therapists, dosimetrists and nurses will observe at least 15 patient treatments, the initial "trainings" occurring at another site. Training will also be provided specific to procedures incorporated into the license application for CCF. This training will also be received by a replacement to any of these identified individuals. At least annually a refresher training will be provided which addresses any significant changes in duties, regulations, terms of the license, equipment, or procedures. Radiation Safety shall ensure all individuals are properly trained and will maintain documentation of the training at least until termination of this license.

Item 8.1.1. (cont.)

For nonhuman use any one of the individuals listed in Item 7 either a physicians or physicists will be present during the operation of the unit.

8.1.2., 8.1.3, 8.1.4, and 8.1.5 - see Attachment 5.

8.3 - see Attachment 5. (no 8.2 identified in draft guide)

Item 9 - Facilities and Equipment

9.1 Facility diagram

See Attachment 6 for annotated plans and elevation drawings. All concrete indicated is standard density 147 pounds/cubic foot. The proposed location is a new one story building with no basement. The door to the treatment room is an electrically powered door which can only be opened when the control panel is "on". To secure entry to the treatment room when unattended the key to the control panel is removed therefore no entry to the treatment room will be possible. This is on emergency back-up power in the event of a power failure.

9.2 Survey Instruments and Radiation Monitors

- A dedicated portable survey meter meeting the requirements of 10 CFR 35.620 will be available in the GSR area. Survey meters will be calibrated at least annually by Radiation Safety using the Victoreen Tech Ops, Cesium-137 calibrator (NRC License 34-00466-01), records of which will be maintained by Radiation Safety for at least 3 years.
- A permanently installed radiation monitor, with an independent source of backup power, will be in use at all times the system is operated. The monitor will produce a flashing light during source out conditions and will be visible upon entry into the treatment room. Verification of performance of this system will be conducted each day the system is to be operated. Results of these checks will be documented and retained for a period of at least 3 years.
- A dosimetry system meeting the requirements in 10 CFR 35. 630 will be used for full calibrations and spot checks. Records of the calibrations of the dosimetry system will be maintained at least through the use of the equipment.
- Equipment available in Radiation Safety for evaluation of leak test samples includes a Tennelec LB 5100 Low background proportional counter equipped with a gamma option (NaI detector); a sodium iodide detector and multichannel analyzer system; or a Beckman 4000 Gamma Counter. All systems provide the ability to detect less than or equal to 0.005 μCi .

(no 9.2, 9.3 or 9.4 identified in draft guide)

9.5 Temporary Hot Cell Construction and Source Loading

For the Leksell Gamma System Model 23004 Type B, construction of a temporary hot cell for loading the 201 sources is no longer required. A dedicated loading machine is utilized to load the sources. Erecting of the loading machine and loading of the sources will be carried out under the supervision of Elekta personnel. The RSO will be present during the loading procedure. Attachment 7 is a copy of Georgia Radioactive Materials License issued to Elekta Radiosurgery, Inc. and Attachment 8 is a copy of the operating procedures for the loading/unloading of the sources.

9.6 Viewing system

A closed circuit television with monitor will be used to continuously view the patient. Two cameras will be located in the treatment room and two monitors will be located outside the treatment room, one at the control area, the other in the planning area. These systems are independent of each other, however if both systems would fail simultaneously, treatment would be halted or postponed until one of the systems is operational.

9.7 Warning Systems and Access Controls

The treatment room door will be posted with a "Caution - High Radiation Area" sign. A warning light will be above the treatment door which will be illuminated when the device is in the treatment position ("beam-on"). The unit will be secured, the key removed, when unattended. The treatment room will be inoperable during non-working hours. The door to the treatment room will be interlocked to control the "on-off" mechanism of the GSR unit. The interlock will return the unit to the non-treatment position if the door is opened when "the sources are exposed". Restarting the unit will require closing the door and performing a "reset" at the control panel. No other radiation-producing equipment will be located in the treatment room.

9.8 Adequacy of Shielding - See Attachment 9.

Item 10 Radiation Safety Program

10.21 Emergency Instructions

See Attachment 10. These will be posted at the GSR unit console.

10.22 GSR Survey Reports

Radiation surveys required by 10 CFR 35.641 will be coordinated and supervised by the Radiation Safety Officer. The RSO has the responsibility for the filing of the survey results with the NRC within 30 days of completion of the survey, incorporating all required information as outlined in 10 CFR 35.641.

The Cleveland Clinic Foundation
Gamma Knife License Application
August 22, 1996
Page 7

10.23 Operating Procedures for GSR - See Attachment 11.

Item 11 Waste Disposal

At the end of the useful life of GSR sources or the entire unit will be transferred only to an authorized recipient (manufacturer) for disposal in accordance with the requirements in 10 CFR 20. The RSO will be responsible for ensuring recipient is authorized to perform these services and accept the sources.

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Roger M. Macklis, M.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (if physician) Ohio	
3. CERTIFICATION			
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED	
American Board of Radiology	Radiation Oncology	June 1989	
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED DUTY/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)			
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE
<small>*Experience with sealed radioactive sources under the supervision of qualified instructors should include:</small>			
1. Review of initial source calibration and periodic spot-check measurements of teletherapy units. 2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes. 3. Calibration of ion chambers and survey meters.		4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy. 5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.	
6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)			
TYPED OR PRINTED NAME			DATE
NAME OF INSTITUTION			
MAILING ADDRESS			
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER
WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.			

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER John H. Suh, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician) Ohio
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Radiation Oncology	June 1995

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED DJT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

*Experience with sealed radioactive sources under the supervision of qualified instructors should include:

- | | |
|---|--|
| 1. Review of initial source calibration and periodic spot-check measurements of teletherapy units.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters. | 4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|---|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

	DATE		
TYPED OR PRINTED NAME			
NAME OF INSTITUTION			
MAILING ADDRESS			
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Jay P. Ciezki, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (if physician) Ohio
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Radiation Oncology	June 1996

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED QJT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

- *Experience with sealed radioactive sources under the supervision of qualified instructors should include:
1. Review of initial source calibration and periodic spot-check measurements of teletherapy units.
 2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
 3. Calibration of ion chambers and survey meters.
 4. Preparation of treatment plans and treatment times for brachytherapy and brachytherapy.
 5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

 TYPED OR PRINTED NAME DATE

NAME OF INSTITUTION

MAILING ADDRESS

CITY STATE ZIP CODE RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Roger M. Macklis, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician) Ohio
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Radiation Oncology	June 1989

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OJT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

*Experience with sealed radioactive sources under the supervision of qualified instructors should include:

- | | |
|---|--|
| 1. Review of initial source calibration and periodic spot check measurements of teletherapy units.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters. | 4. Preparation of treatment plans and treatment times for brachytherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|---|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

TYPED OR PRINTED NAME	DATE
NAME OF INSTITUTION	
MAILING ADDRESS	
CITY	STATE ZIP CODE RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician)	
John H. Suh, M.D.		Ohio	
3. CERTIFICATION			
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED	
American Board of Radiology	Radiation Oncology	June 1995	
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
RADIATION PHYSICS AND INSTRUMENTATION		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OJT/LABORATORY EXPERIENCE (Hours)
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)			
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE
<p style="text-align: center; font-size: small;">*Experience with sealed radioactive sources under the supervision of qualified instructors should include:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>1. Review of initial source calibration and periodic spot check measurements of teletherapy units.</p> <p>2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.</p> <p>3. Calibration of ion chambers and survey meters.</p> </div> <div style="width: 48%;"> <p>4. Preparation of treatment plans and treatment times for ⁶⁰Co, ¹⁹²Ir, and brachytherapy.</p> <p>5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.</p> </div> </div>			
6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)			
TYPED OR PRINTED NAME _____			DATE _____
NAME OF INSTITUTION _____			
MAILING ADDRESS _____			
CITY _____	STATE _____	ZIP CODE _____	RADIOACTIVE MATERIALS LICENSE NUMBER _____
WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.			

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Jay P. Ciezki, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician) Ohio
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Radiation Oncology	June 1996

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OUT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Activities with radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

- *Experience with sealed radioactive sources under the supervision of qualified instructors should include:
- | | |
|---|--|
| 1. Review of initial source calibration and periodic spot check measurements of teletherapy units.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters. | 4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|---|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

	DATE
TYPED OR PRINTED NAME	
NAME OF INSTITUTION	
MAILING ADDRESS	
CITY	STATE ZIP CODE
RADIOACTIVE MATERIALS LICENSE NUMBER	

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Martin S. Weinhaus, Ph.D.			2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician)	
3. CERTIFICATION				
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED		
American Board of Radiology	Therapeutic Radiological Physics	June 1989		
American Board of Medical Physics	Radiation Oncology Physics	October 1990		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)				
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING		
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED QIT/LABORATORY EXPERIENCE (Hours)	
RADIATION PHYSICS AND INSTRUMENTATION				
RADIATION PROTECTION				
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES				
RADIATION BIOLOGY				
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
<p style="text-align: center; font-size: small;">*Experience with sealed radioactive sources under the supervision of qualified instructors should include:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>1. Review of initial source calibration and periodic spot check measurements of brachytherapy units.</p> <p>2. Initial source calibration of sealed sources other than brachytherapy sources that are used for treatment purposes.</p> <p>3. Calibration of ion chambers and survey meters.</p> </div> <div style="width: 48%;"> <p>4. Preparation of treatment plans and treatment times for ¹⁹²Ir, ⁶⁰Co, and brachytherapy.</p> <p>5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.</p> </div> </div>				
6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)				
TYPED OR PRINTED NAME				DATE
NAME OF INSTITUTION				
MAILING ADDRESS				
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER	
<p style="font-size: x-small;">WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.</p>				

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Firman Christopher Deibel, Ph.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician)
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Therapeutic Radiological Physics	June 1987

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OUT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

*Experience with sealed radioactive sources under the supervision of qualified instructors should include:

1. Review of initial source calibration and periodic spot check measurements of teletherapy units.
4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.
3. Calibration of ion chambers and survey meters.

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

TYPED OR PRINTED NAME	DATE
NAME OF INSTITUTION	
MAILING ADDRESS	
CITY	STATE ZIP CODE RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

Attachment 3

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Judy A. McKenna, M.S.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician) N/A
--	--

SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
The American Board of Radiology	Diagnostic & Medical Nuclear Physics	June, 1992

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OJT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

*Experience with sealed radioactive sources under the supervision of qualified instructors should include:

- | | |
|---|--|
| 1. Review of initial source calibration and periodic spot check measurements of teletherapy units.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters. | 4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|---|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program supervisor)

TYPED OR PRINTED NAME	
NAME OF INSTITUTION	
MAILING ADDRESS	
CITY	STATE
ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

The Cleveland Clinic Foundation
Gamma Knife License Application

August 22, 1996

Attachment 4

SUPPLEMENT A

TRAINING AND EXPERIENCE

PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Martin S. Weinhaus, Ph.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (if physician)	
3. CERTIFICATION			
SPECIALTY BOARD		CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology		Therapeutic Radiological Physics	June 1989
American Board of Medical Physics		Radiation Oncology Physics	October 1990
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OUT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)			
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE
<p>*Experience with sealed radioactive sources under the supervision of qualified instructors should include:</p> <div style="display: flex; justify-content: space-between;"> <div> <p>1. Review of initial source calibration and periodic spot-check measurements of brachytherapy units.</p> <p>2. Initial source calibration of sealed sources other than brachytherapy sources that are used for treatment purposes.</p> <p>3. Calibration of ion chambers and survey meters.</p> </div> <div> <p>4. Preparation of treatment plans and treatment times for intracavitary and brachytherapy.</p> <p>5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.</p> </div> </div>			
6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program submitter)			
TYPED OR PRINTED NAME			DATE
NAME OF INSTITUTION			
MAILING ADDRESS			
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER
<p>WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.</p>			

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Firman Christopher Deibel, Ph.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician)
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
American Board of Radiology	Therapeutic Radiological Physics	June 1987

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)			
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE (Hours)	FORMAL SUPERVISED OUT/LABORATORY EXPERIENCE (Hours)
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

- *Experience with sealed radioactive sources under the supervision of qualified instructors should include:
- | | |
|---|--|
| 1. Review of initial source calibration and periodic spot-check measurements of isotherapy units.
2. Initial source calibration of sealed sources other than isotherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters. | 4. Preparation of treatment plans and treatment times for brachytherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|---|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of program administrator)

TYPED OR PRINTED NAME	DATE
NAME OF INSTITUTION	
MAILING ADDRESS	
CITY	STATE ZIP CODE RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1007, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

The Cleveland Clinic Foundation

Radiation Safety Training

Frequency: As part of the new hire orientation, a brief introduction to the role of Radiation Safety is provided. Individuals are instructed how to contact Radiation Safety and encouraged to do so with any questions which may arise. Prior to assuming responsibilities involving the use of radioactive material or radiation-producing equipment, training commensurate with assigned duties will be performed. At least annually, refresher training will be provided for individuals with handling/operation responsibilities which shall include a review of any significant changes in duties, regulations or terms of applicable licenses.

Note: For individuals who may need to work in an area with radioactive material or radiation-producing equipment who are not employees, i.e. contractors, consultants, etc., training will be commensurate with duties and provided prior to commencing work in the area.

Documentation: Radiation Safety will maintain documentation of training which shall include at a minimum the instructor, contents, attendees and the date. Documentation will be maintained for at least three years.

Contents: Training will be structured to address the needs of the audience, the following will be covered at a minimum with all sessions providing a question/answer period:

For support personnel in an area (building services, security, clerical, etc.):

- Posting/labeling - location of signs in area, control of access, precautions for entry as appropriate, who to contact for additional information.
- Regulations/licenses - locations, availability, who to contact with questions.
- Unusual occurrences - immediate actions and who to contact.
- Obligation to report unsafe conditions to Radiation Safety.

For nursing personnel providing care to patients - in addition to the above:

- Basic radiation biology and radiation physics as applicable, to include time, distance and shielding.
- Risk estimates, including comparison with other health risks.
- ALARA concept.
- Patient and visitor control as appropriate to include contamination control and waste handling procedures.
- Requirements for personnel monitoring to include proper use, right to be informed of occupational radiation exposure, occupational dose limits, embryo/fetus dose limits, pregnant worker policy, dose to members of the public.
- Quality management program as appropriate.
- Response for medical emergencies or patient death
- Summary of incidents, events and/or accidents and appropriate actions.

For personnel directly handling radioactive material or operating radiation producing equipment - in addition to the above:

- Appropriate surveys to be performed, frequency, documentation and notification requirements.

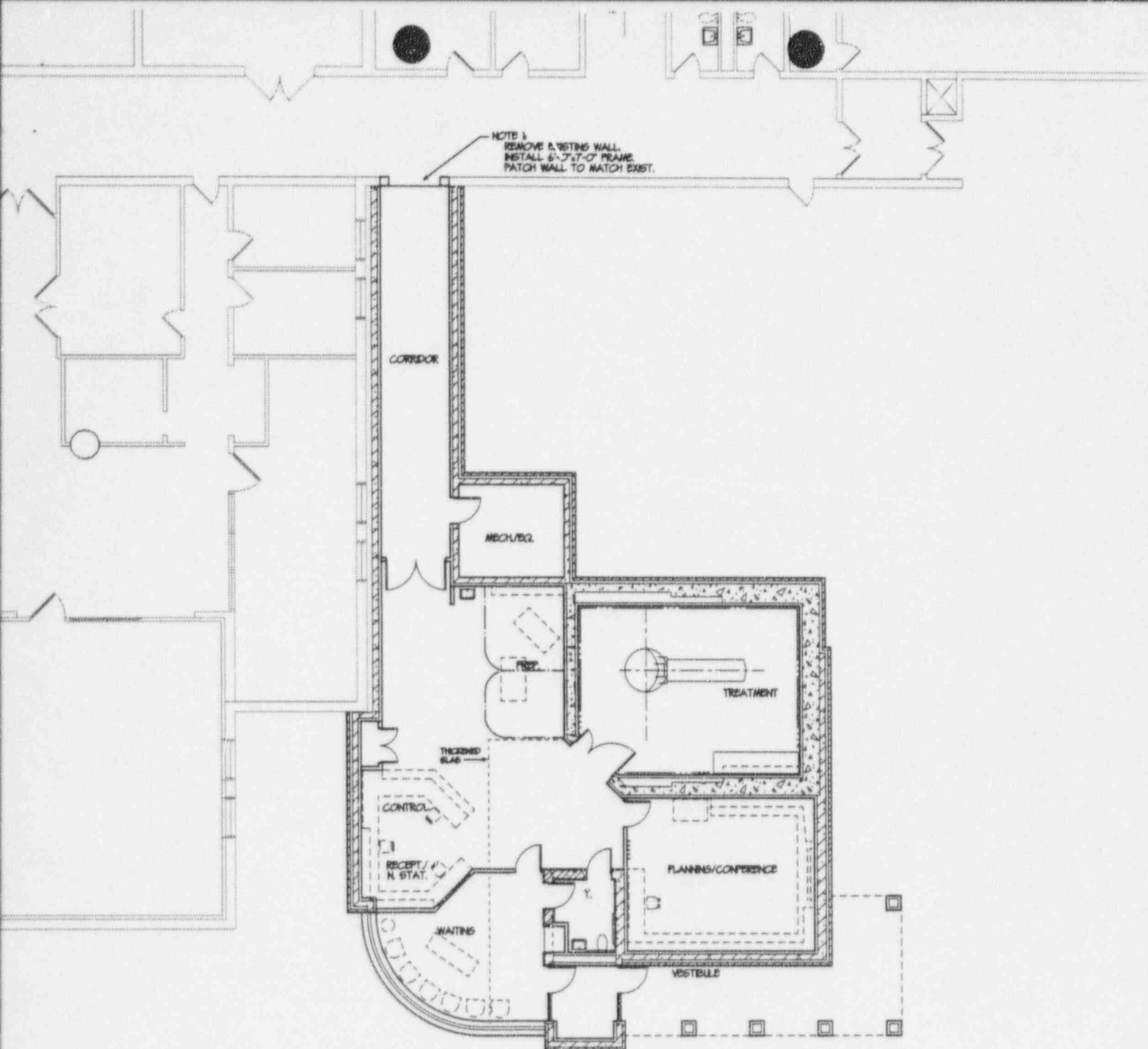
- Operating procedures or safe handling procedures.

- Emergency procedures to include drills as appropriate.

- Regulatory requirements for computerized treatment planning systems and dosimetry protocols as appropriate.

**THE CLEVELAND CLINIC
FOUNDATION
Gamma Knife Center**

**COLLINS, RIMER AND GORDON
ARCHITECTS**



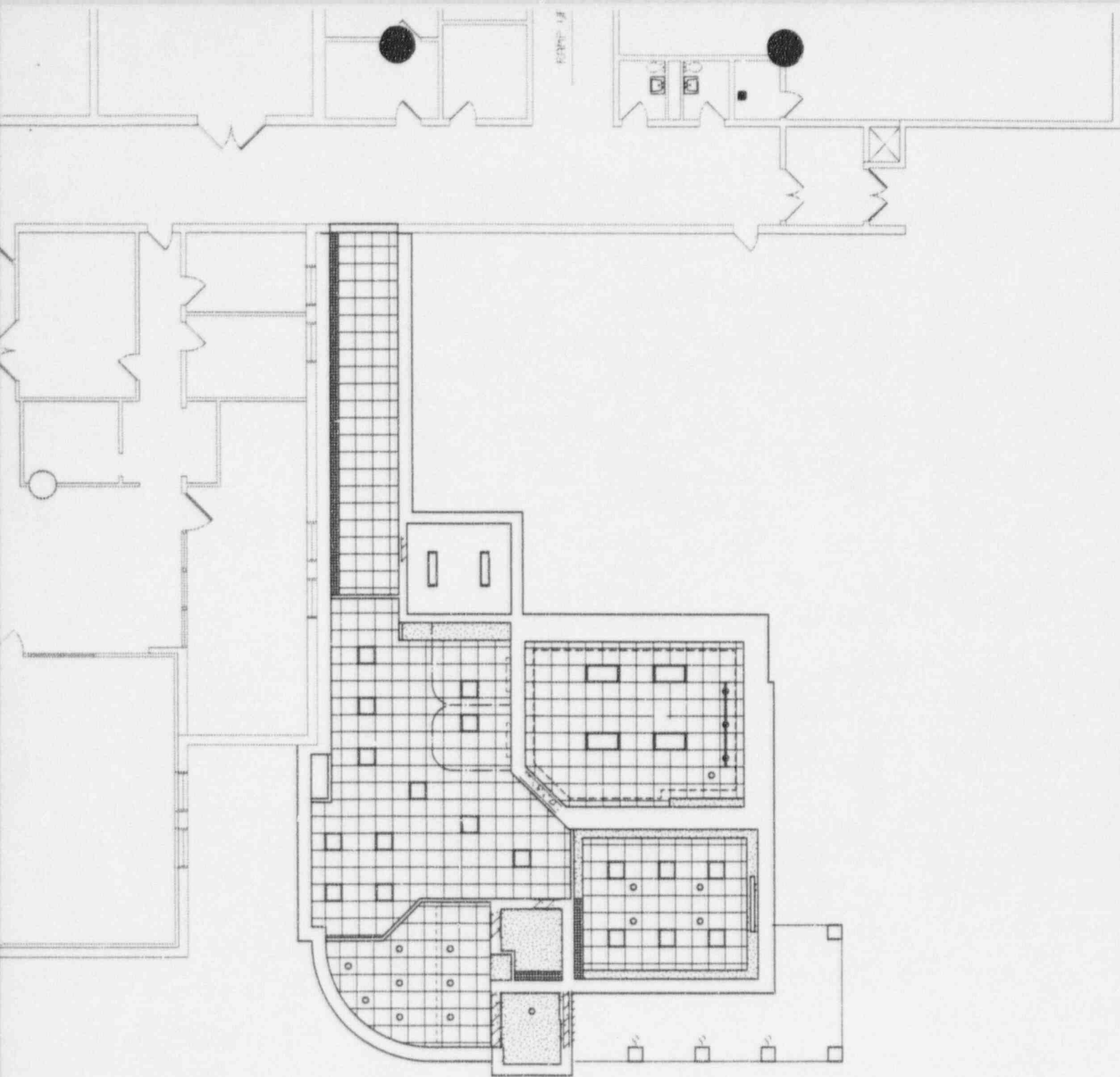
THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

FIRST FLOOR PLAN

1/16" = 1'-0"





THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

FIRST FLOOR REFLECTED CEILING PLAN
1/16"=1'-0"



702

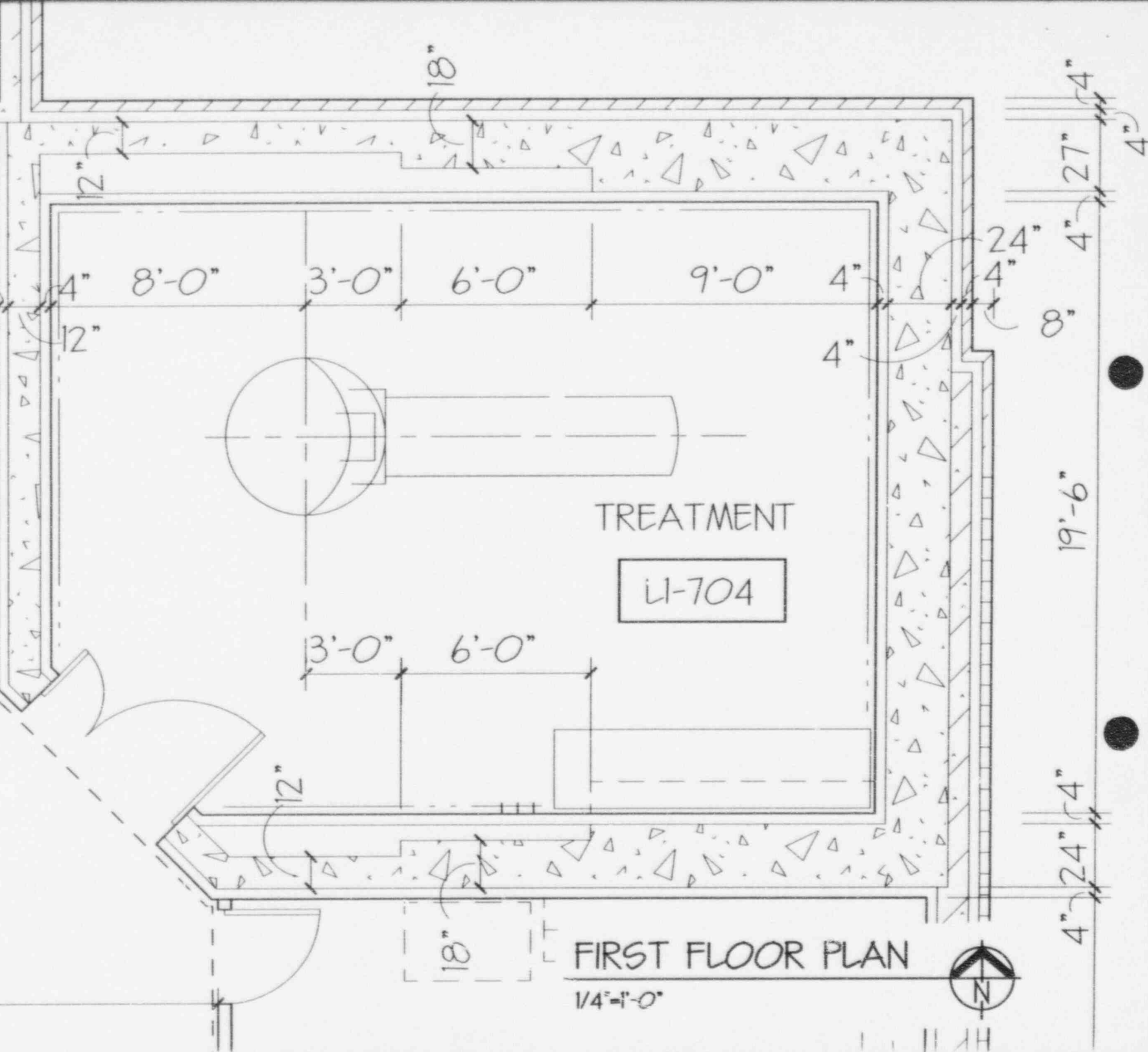
1 1/2"

PREP.

LI-703

2'-2"

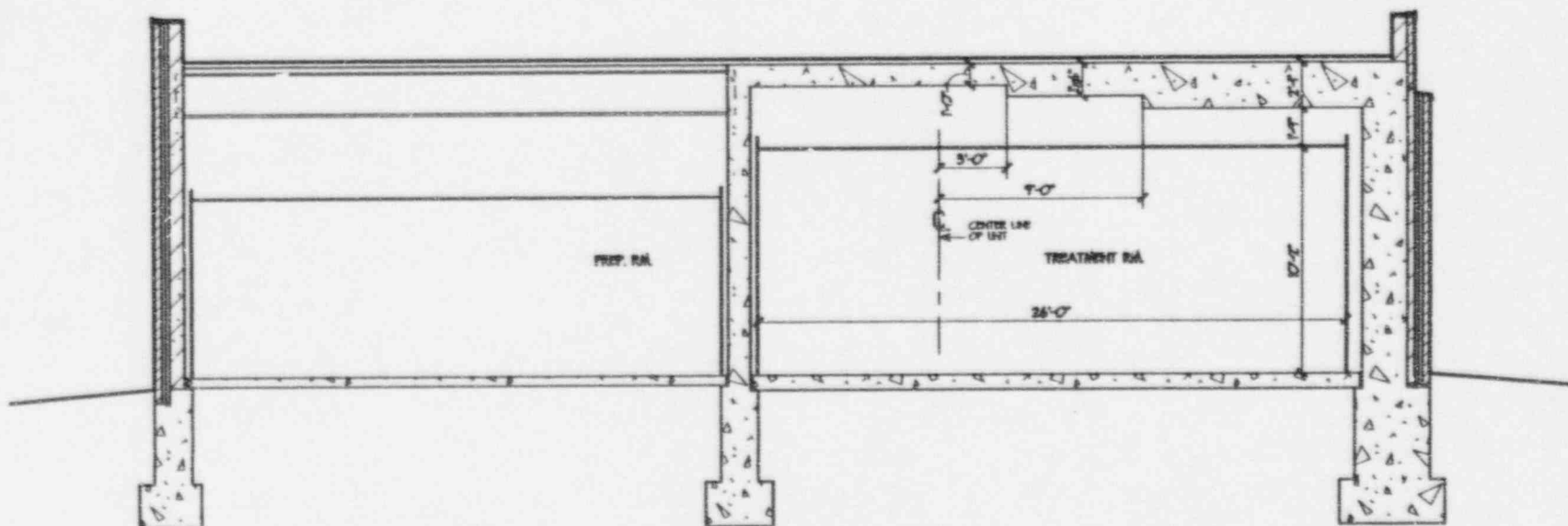
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FIRST FLOOR PLAN

1/4" = 1'-0"



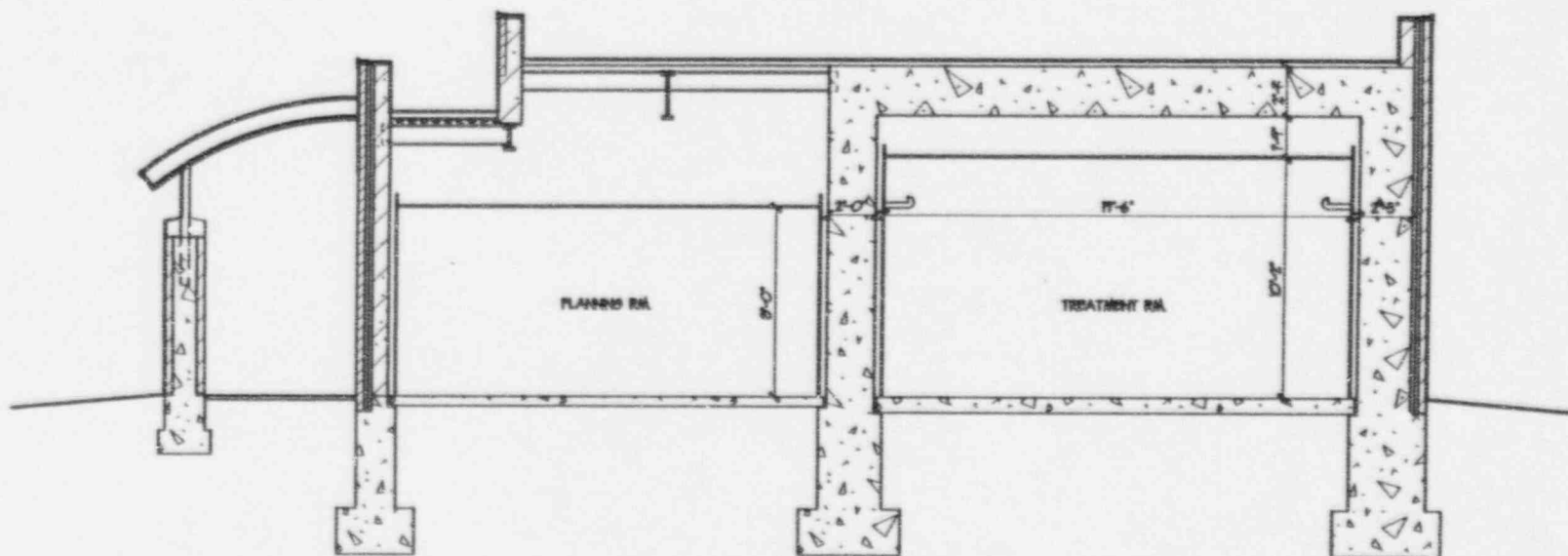


SOUTH SECTION

SCALE: 1/8"=1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

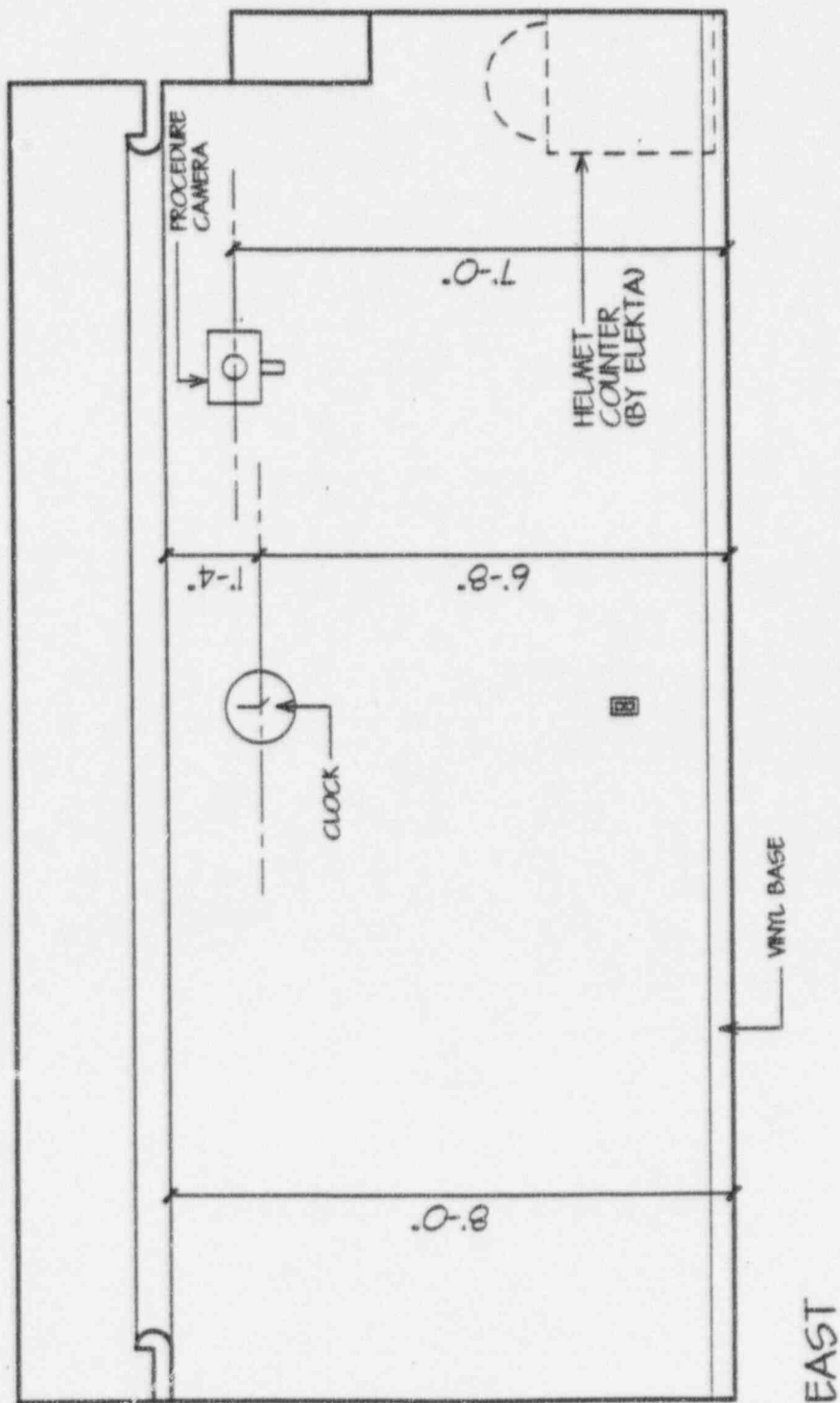


EAST SECTION

SCALE: 1/8"=1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

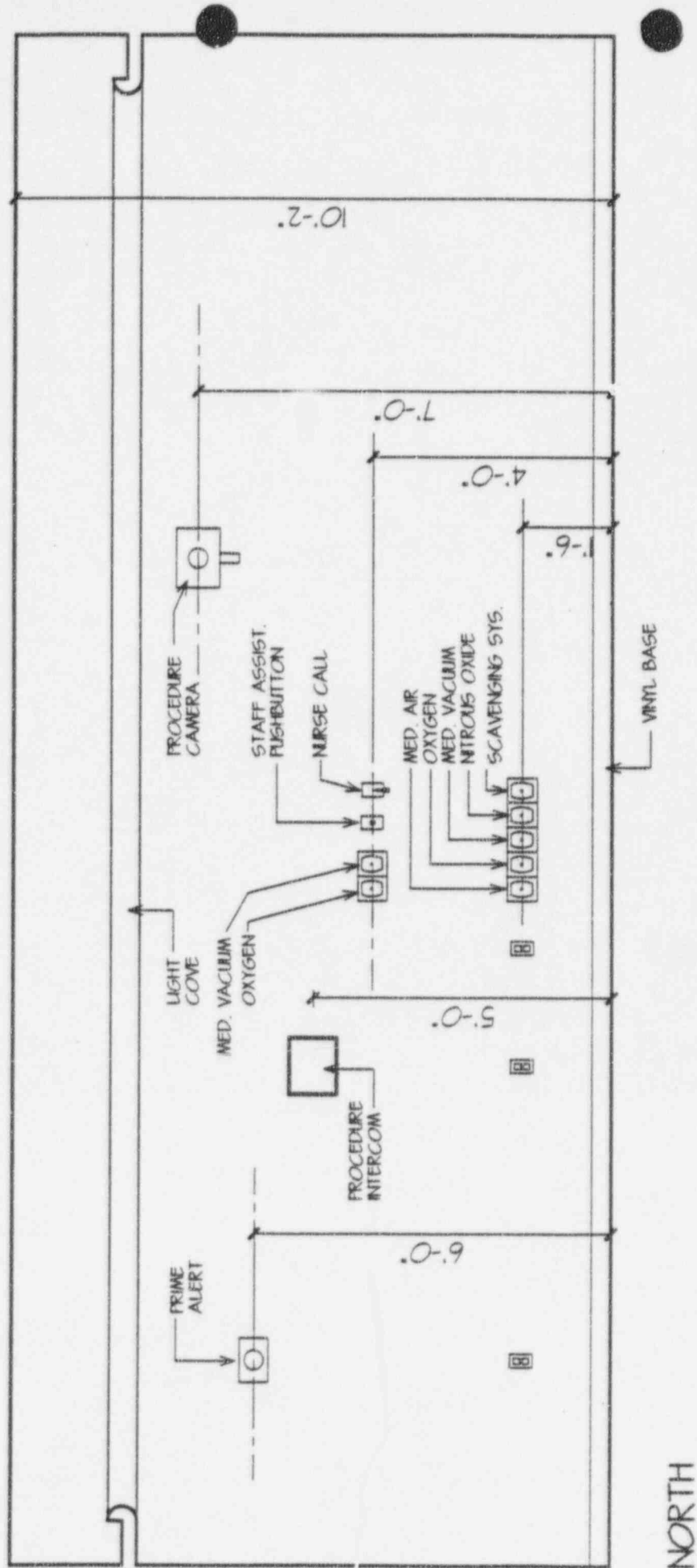


TREATMENT ROOM

3/8" = 1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS



TREATMENT ROOM
 3/8" = 1'-0"

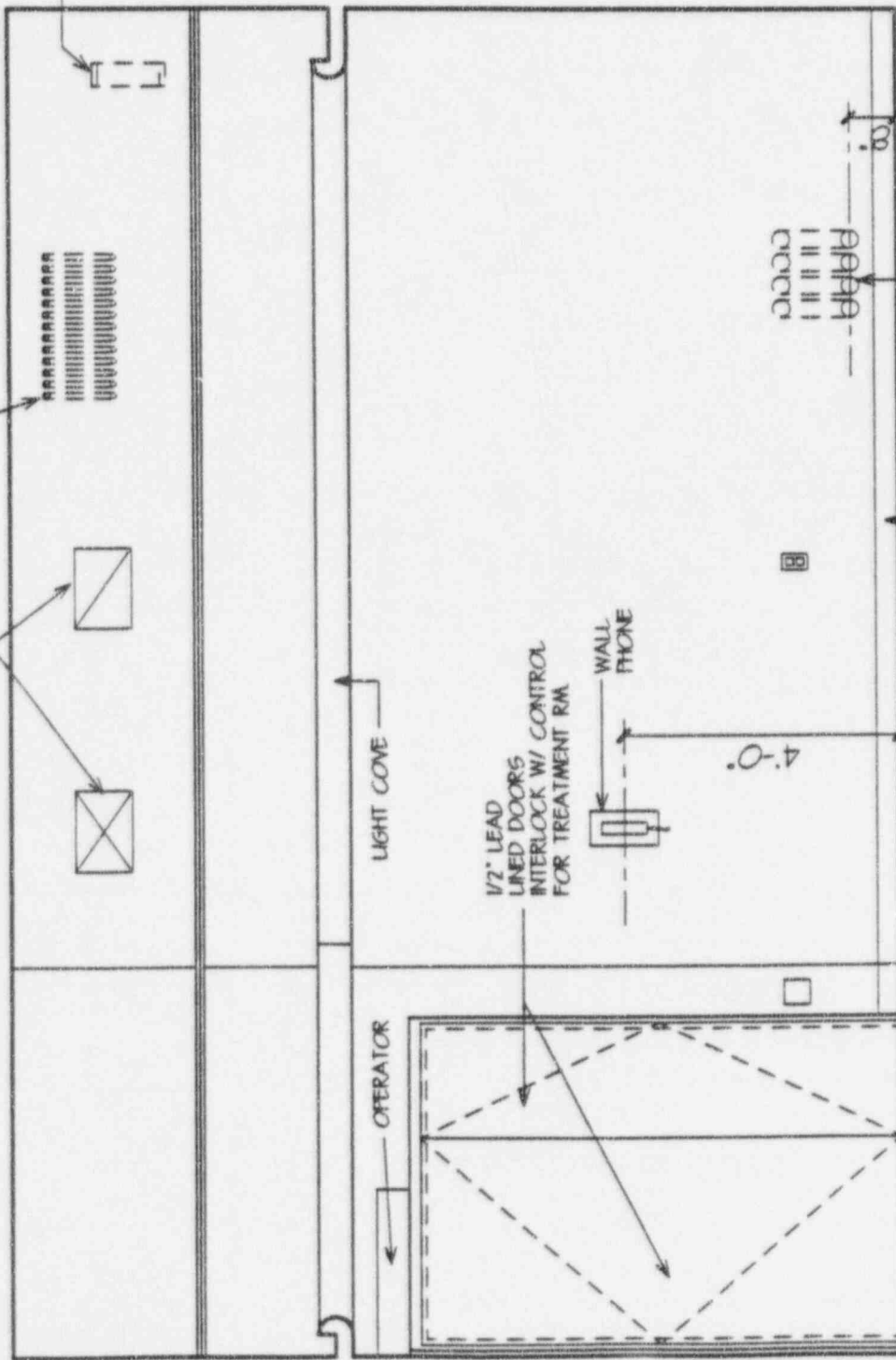
THE CLEVELAND CLINIC FOUNDATION
 GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
 ARCHITECTS

1 @ 3/4" ϕ CONDUITS &
2 @ 1" ϕ CONDUITS
ANGLED @ 45°
IN THE VERTICAL
FROM PREP. RM.

14"x10" A/C DUCTS
LEAD LINED. SEE
MECH. DRWG'S.

4"x4"
FOR MEDICAL
GAS GROUP
ANGLED @ 45°
IN THE VERTICAL
FROM PREP. RM.



(4) 3" ϕ
CONDUIT
ANGLED @ 45°
IN THE VERTICAL
FROM PREP. RM.

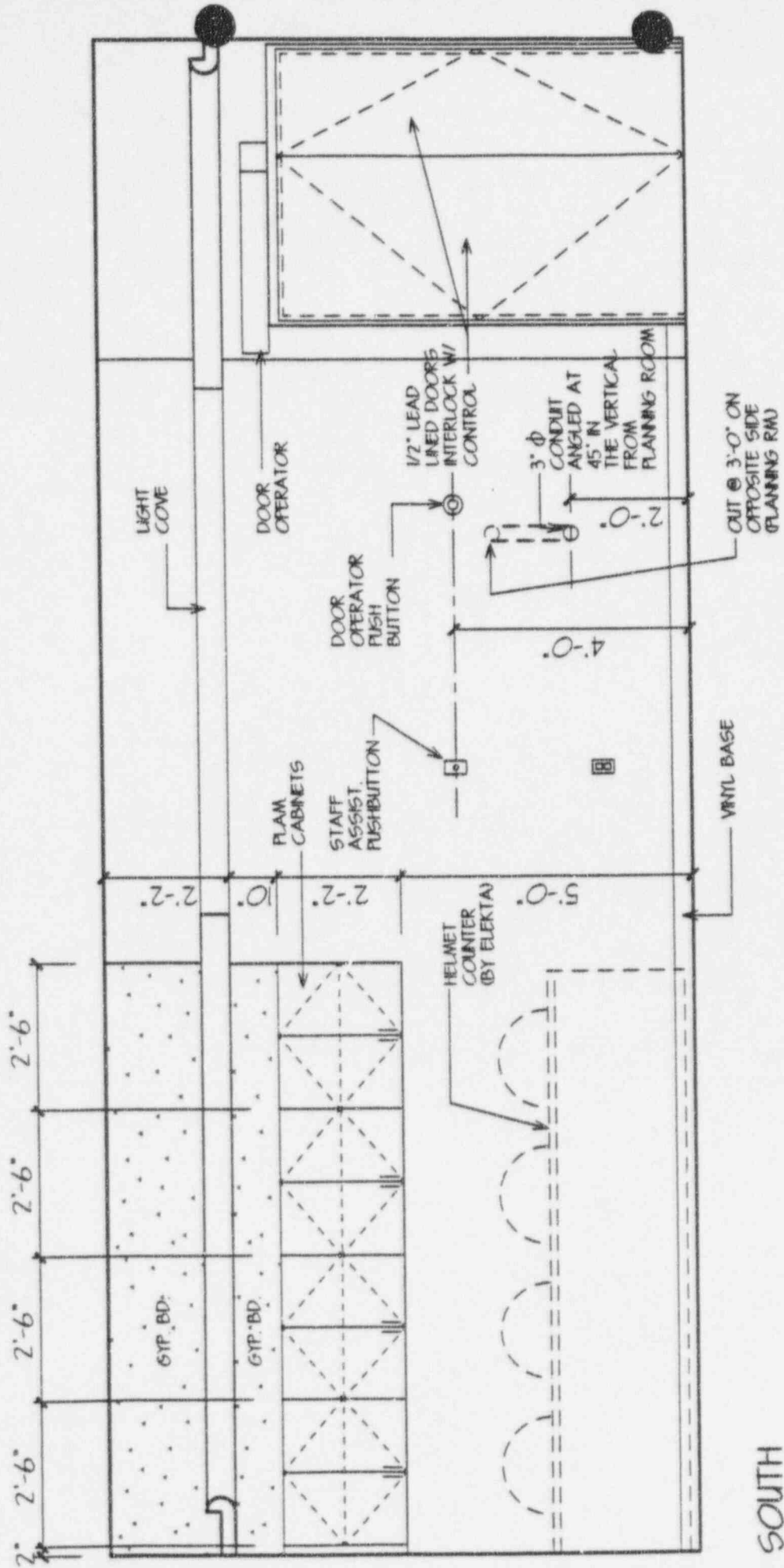
TREATMENT ROOM

3/8" = 1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

WEST

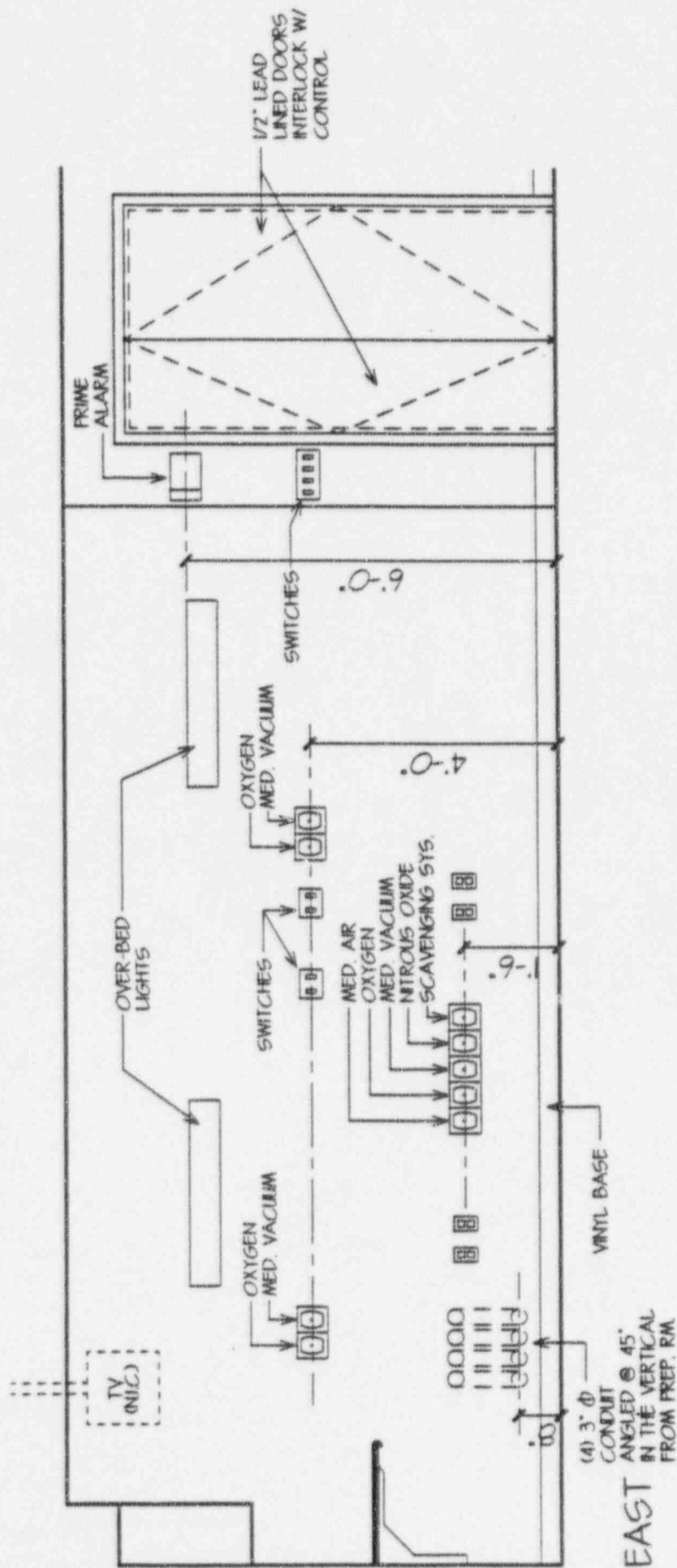


TREATMENT ROOM

3/8" = 1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS

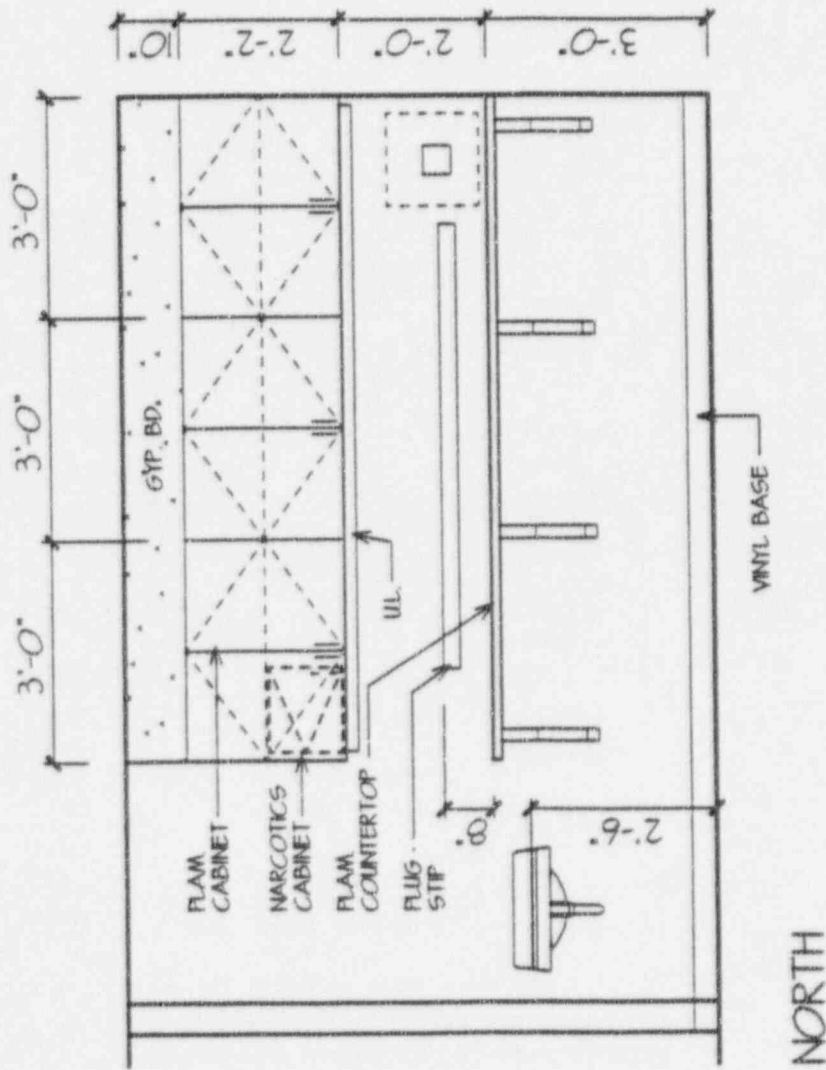


THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

PREP. ROOM

3/8" = 1'-0"

COLLINS, RIMER AND GORDON
ARCHITECTS

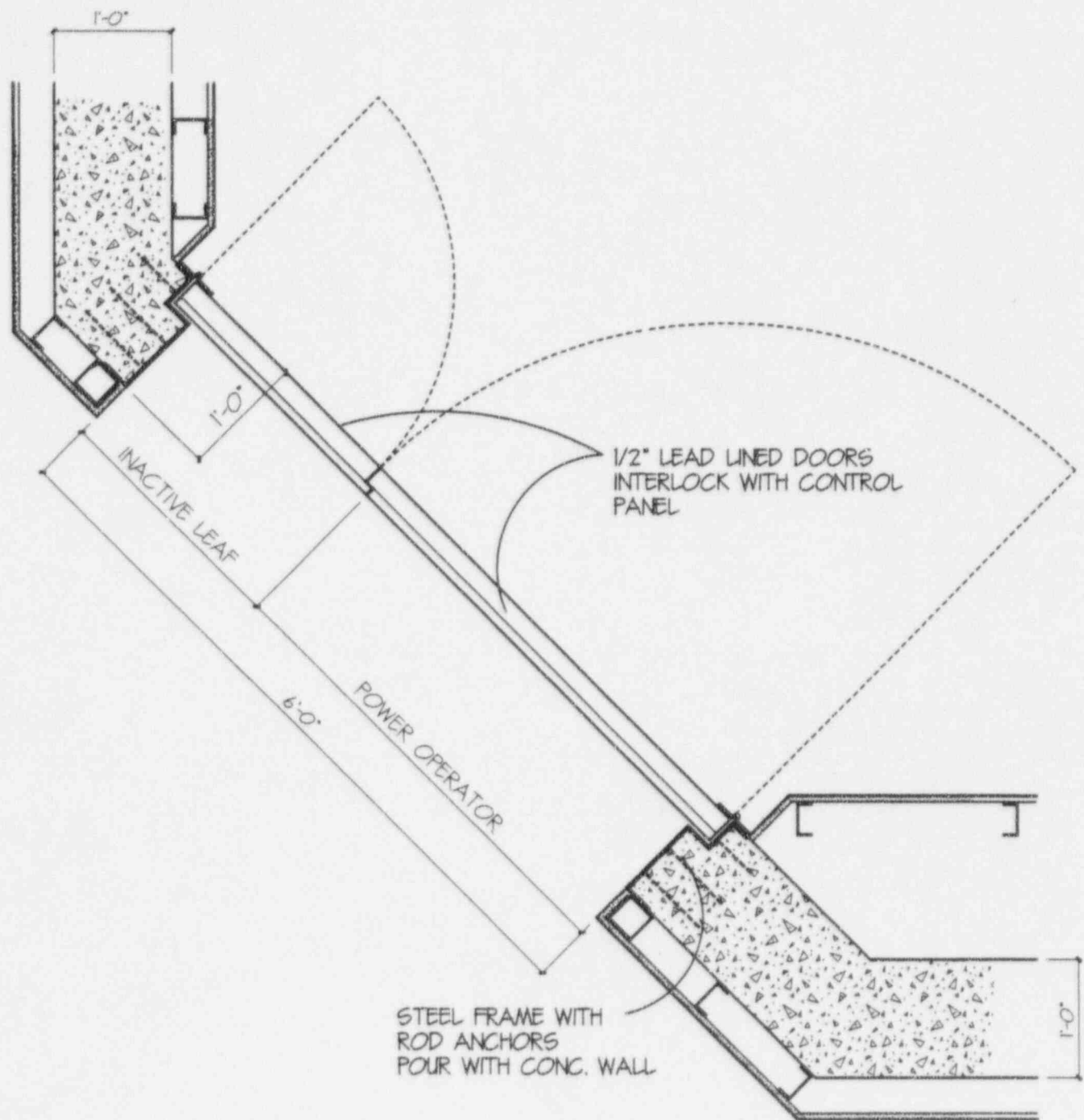


THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

PREP. ROOM

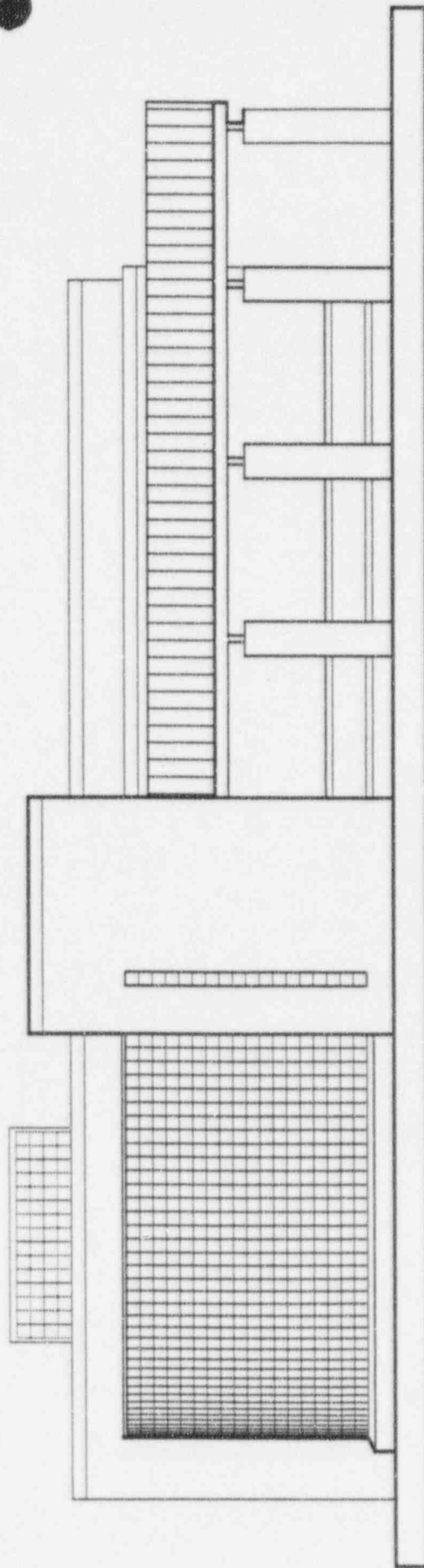
3/8" = 1'-0"

COLLINS, RIMER AND GORDON
ARCHITECTS



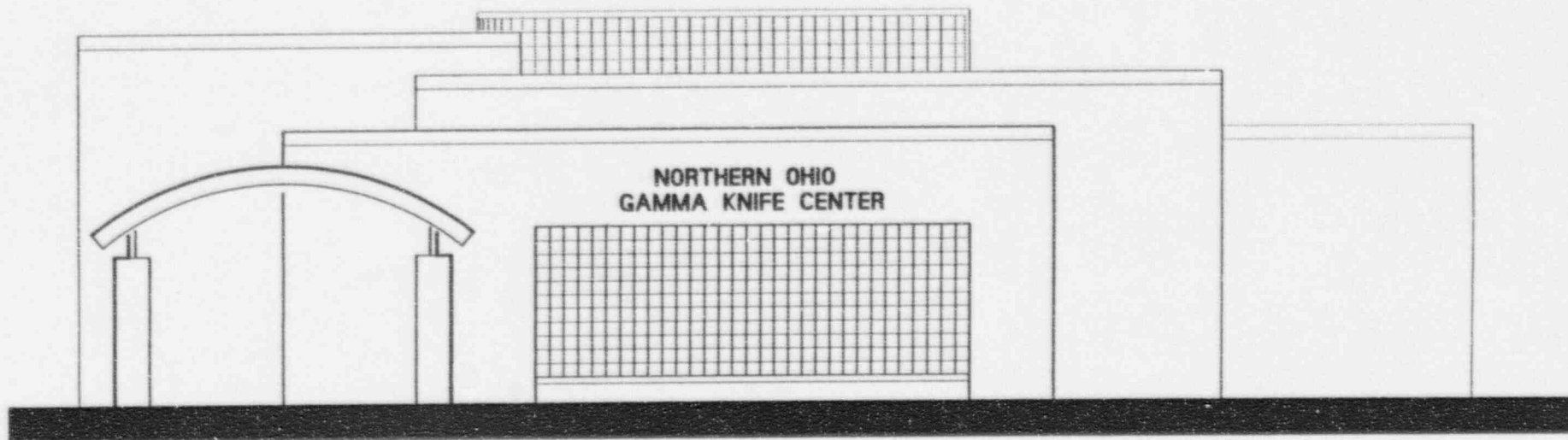
THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

TREATMENT DOOR DETAIL



SOUTH ELEVATION

SCALE: 1/8"=1'-0"



EAST ELEVATION

SCALE: 1/8"=1'-0"

RADIOACTIVE MATERIALS PROGRAM GEORGIA RADIOACTIVE MATERIALS LICENSE

Pursuant to the Georgia Radiation Control Act O.C.G.A. 31-13 (H.B. 947) 1990 and the Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Georgia Department of Natural Resources and orders issued by the Department, now or hereafter in effect, and to any condition specified below.

Page 1 of 3 Pages
License Number GA. 1153-1
Amendment Number .07

License (1. Name and 2. Address)

Elekta Radiosurgery, Inc.
8 Executive Park West
Suite 809
Atlanta, Georgia 30329

3. In accordance with amendment request dated June 23, 1995, License Number GA. 1153-1 is amended in its entirety to read as follows:

4. Expiration Date: June 30, 1999

5. Telephone Number: (404) 315-1225

6. Radioactive Material
(Element and Mass
Number)

7. Chemical and/or
Physical Form

8. Maximum quantity
licensee may utilize at
any one time

A. Cobalt 60

A. Sealed Sources
(General Electric
Company AB Elekta
Model Number 43047)

A. 6600 Curies: 201
sources with a mean
average not to exceed
32.8 Curies, and no
single source to
exceed 36 Curies

B. Cesium 137

B. Sealed Source
(Victoreen Model
Number 541-205)

B. 103 microcuries

9. Authorized Use

A. To be used for installation, relocation, maintenance and loading (source capsules) of Elekta Instruments, Inc., Leksell Gamma System Gamma Knife at existing irradiation equipment installations. The licensee shall strictly abide by all requirements of the customer's license and applicable requirements of the U.S. Nuclear Regulatory Commission or Agreement State within which the authorized work is performed.

B. To be used to calibrate Victoreen Model 541R Pencil Dosimeters.

Georgia Department of Natural Resources

Radioactive Materials License

Supplementary Sheet

Page 2 of 3 Pages

License Number GA 1153-1

Amendment Number 07

Conditions

10. A. Cobalt 60 radioactive material may only be used at facilities of customers in Georgia who possess a valid Georgia Radioactive Materials License for the cobalt-60 sources. This condition does not prohibit use in other Agreement States and States under the jurisdiction of the U. S. Nuclear Regulatory Commission under reciprocity procedures which may be established by an Agreement State or the U. S. Nuclear Regulatory Commission.
- B. Cesium 137 radioactive material may only be used at the licensee's address in Item 2, above.
11. The licensee shall comply with the provisions of the Georgia Department of Natural Resources Rule 391-3-17-.03, "Standards for Protection Against Radiation. Amended.", and with Rule 391-3-17-.07, "Notices, Instructions, and Reports to Workers: Inspections. Amended."
12. In accordance with DNR Board Policy adopted May 27, 1992, the fees associated with this license fee category, F., are:
- | | | | |
|-----------------|--------|----------------------------|-------|
| Annual fee | \$1500 | Amendment fee | \$630 |
| Application fee | \$1400 | Routine Inspection fee | \$800 |
| Renewal fee | \$1100 | Non-routine Inspection fee | \$690 |

Checks for the fees should be made payable to the Department of Natural Resources, Radioactive Materials Program and mailed to the following address:

Radioactive Materials Fees
P.O. Box 101161
Atlanta, Georgia 30392

Mail license applications, amendments and renewal request the same day as the check to the following address:

Radioactive Materials Program
4244 International Parkway, Suite 114
Atlanta, Georgia 30354

Renewal and amendment fees must accompany each licensure request, as appropriate. Inspection fees are payable upon receipt of each invoice from the Department following inspections. Annual fees are billed by the Department at the beginning of each fiscal year.

13. A. Installation, relocation, removal, maintenance, repair and operation testing of Elekta Instruments, Inc., Leksell Gamma System Gamma Knife shall be done by or under the supervision of J. Rod Mason, Martin Knotts, Ulf Pettersson, or Billy Andersson.

Georgia Department of Natural Resources

Radioactive Materials License

Supplementary Sheet

Page 3 of 3 Pages

License Number GA. 1153-1

Amendment Number 07

Condition 13 (Continued)

- B. Loading and unloading source capsules of Leksell Gamma units shall be done by Martin Knotts or Ulf Pettersson.
- 14. The Radiation Safety Officer in this program shall be J. Rod Mason.
- 15. Sealed sources shall be loaded into the Leksell Gamma Unit by persons authorized by the Department, the U. S. Nuclear Regulatory Commission, or any Agreement State to perform such services.
- 16. A. Relocation of the unit within the treatment rooms that could result in increased radiation levels in areas outside the teletherapy treatment rooms shall be evaluated by a radiation survey made as described in Elekta's Radiation Safety Instructions in letter dated June 14, 1994.
B. Relocation of the Leksell Gamma Unit to a new treatment room or facility is not permitted except as authorized by the customer's license.
- 17. This license does not authorize the possession of cobalt 60.
- 18. All records or copies of records pertaining to Radioactive Material License Number GA. 1153-1 shall be maintained by the Radiation Safety Officer at the address in Item 2.
- 19. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:
 - A. By transfer of waste to an authorized recipient;
 - B. By transfer to a specifically licensed recipient; or
 - C. As provided otherwise by specific condition of this license pursuant to the requirements of (12) of Rule 391-3-17-.03.
- 20. Except as specifically provided otherwise in this license, the licensee shall conduct his program in accordance with statements, representations, and procedures contained in the documents, including any enclosures, listed below:
 - A. Application dated May 31, 1994, signed by Martin Knotts, Project Manager;
 - B. Letter dated June 14, 1994, and facsimile received June 30, 1994, signed by Martin Knotts, Project Manager; and

Georgia Department of Natural Resources
Radioactive Materials License
Supplementary Sheet

Condition 20 (Continued)

- C. Letters dated January 5, 1995 and March 9, 1995, signed by Martin Knotts, Project Manager.
- D. Letter dated June 23, 1995, signed by Martin Knotts, Project Manager.

The Georgia Department of Natural Resources' Regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.

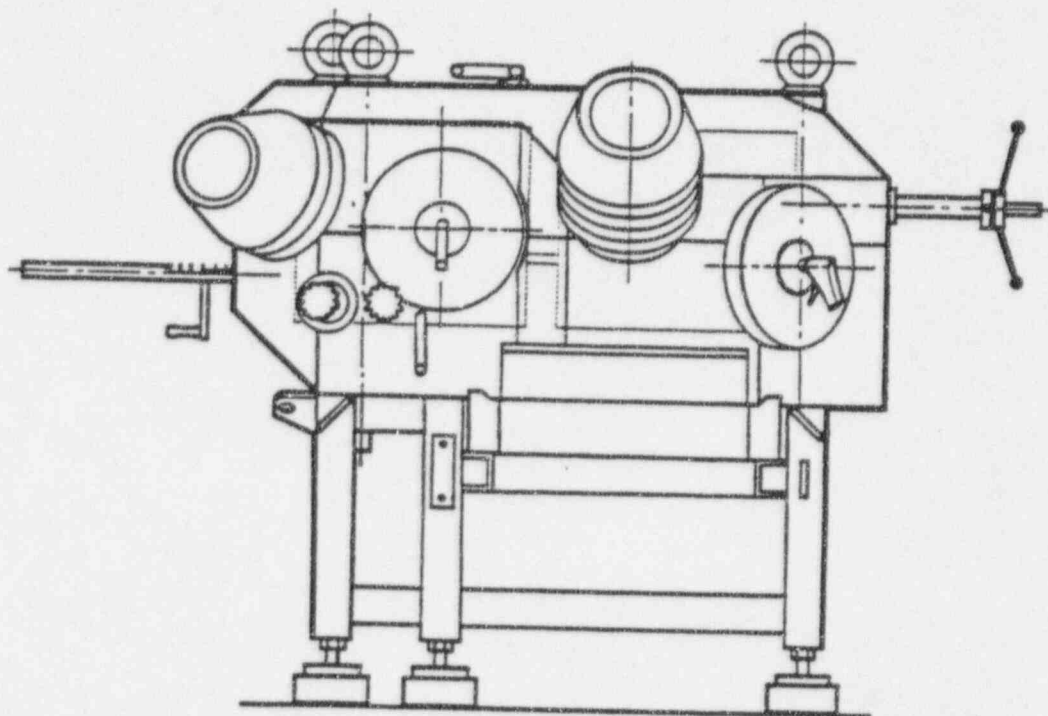
FOR THE DEPARTMENT OF NATURAL RESOURCES

Date June 28, 1995

BY *W. H. Capeland for Thomas E. Hill*

PART 3

LOADING/UNLOADING CO-60 SOURCES



ELEKTA LOADER

Loading and Unloading
Cobalt Sources

in
Leksell Gamma Knife
Type B



ELEKTA

Contents

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A. Introduction

The Gamma Knife may be loaded with radiation sources only by trained technicians in the Gamma Knife loading team. The procedure usually takes place in the treatment room: the loading machine is assembled, the sources inserted and the loading machine dismantled.

Due to the heavy weight of the loading equipment (Gamma knife, loading machine and cask), the loading room must be able to withstand an additional weight of 35 metric tons and must be dimensioned to accommodate the equipment shown in Fig. 1.

The cask in its transport encapsulation, including all the sources, is separately shipped to the site.

A1. The Loading Machine

The loading machine, which is a shielded cell, is designed for handling radiation sources with full radiation safety. It is built almost entirely of lead and weighs about 12 metric tons - see Fig. 2.

The machine is delivered with certain components dismantled. These are shipped in three transport cases fixed in a container in which the machine is also secured - Fig. 3. The component parts are assembled into one unit at the location where loading is to take place - see Chapter B. Assembling the Loading Machine.

The cask frame and installation stand, as well as its radiation shield, are also included in the container.

A2. Radiation Sources

Each of the 201 radiation sources consists of around 20 Co-60 pellets having a diameter of 1 mm and a length of 1 mm. The pellets are encased in double stainless steel capsules with welded closures. The sources comply with ANSI standard N-542 for medical radiotherapy sources.

At loading time, the specific activity of each Co-60 Source is around 250 Ci/g. Total activity is between 5400 and 6600 Ci.

The sources are delivered in a specially designed, approved container, a cask. Two different types of cask are available - Croft and Alpha-Omega. Each radiation source is individually registered and the radiation activity for each is prerecorded in a loading diagram. The sources must be inserted into the radiation unit strictly in accordance with this loading diagram.

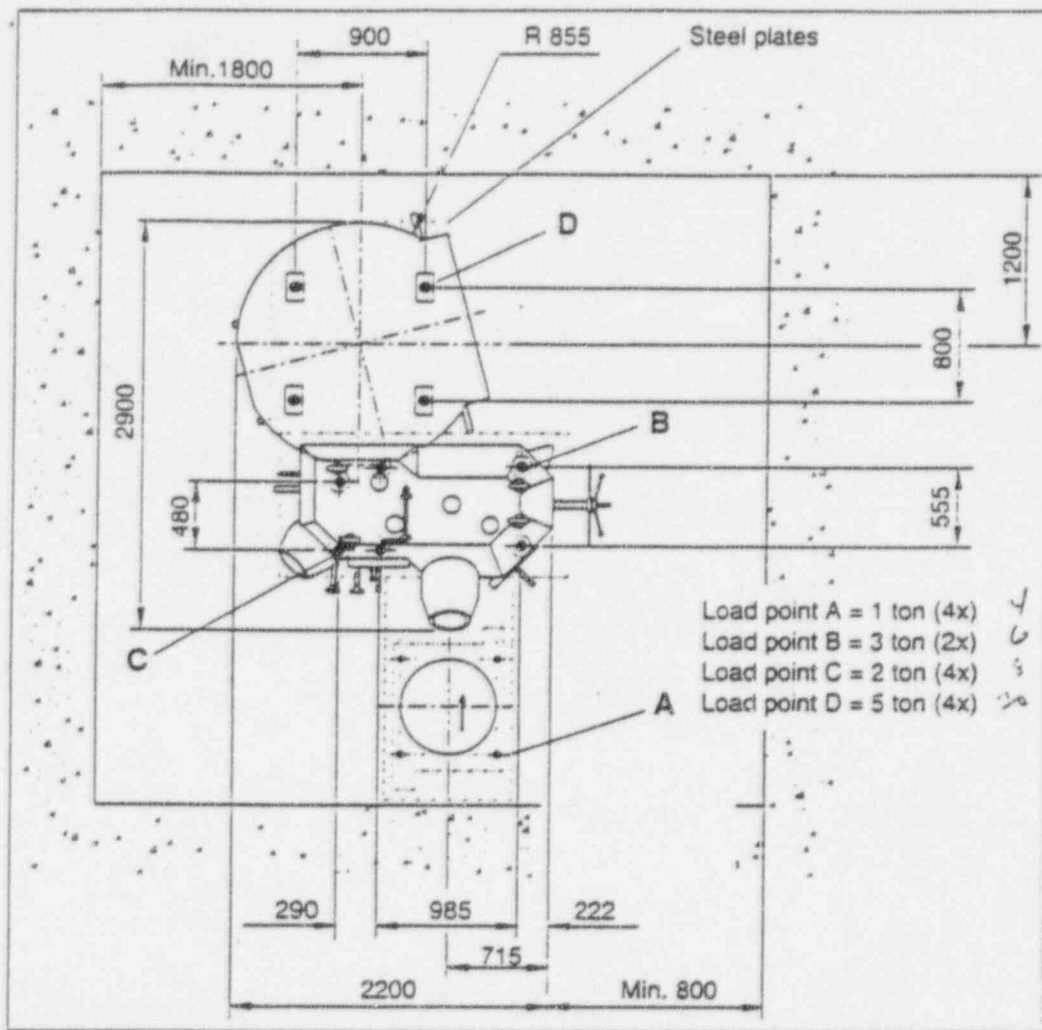


Fig. 1 Loading room data and dimensions

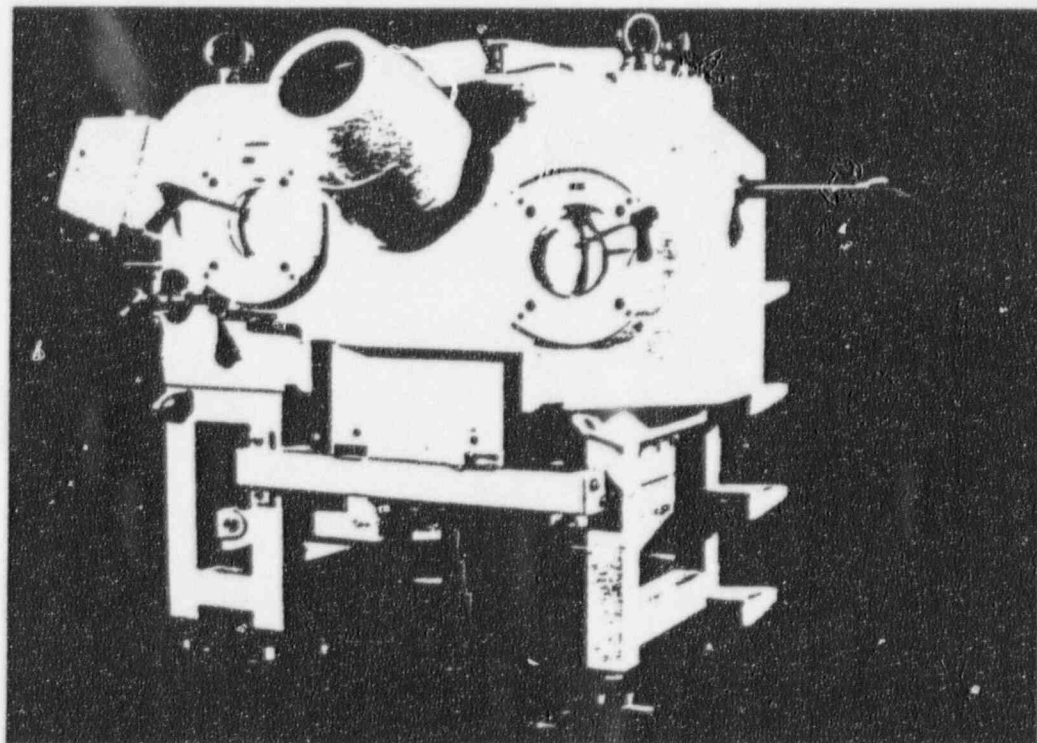
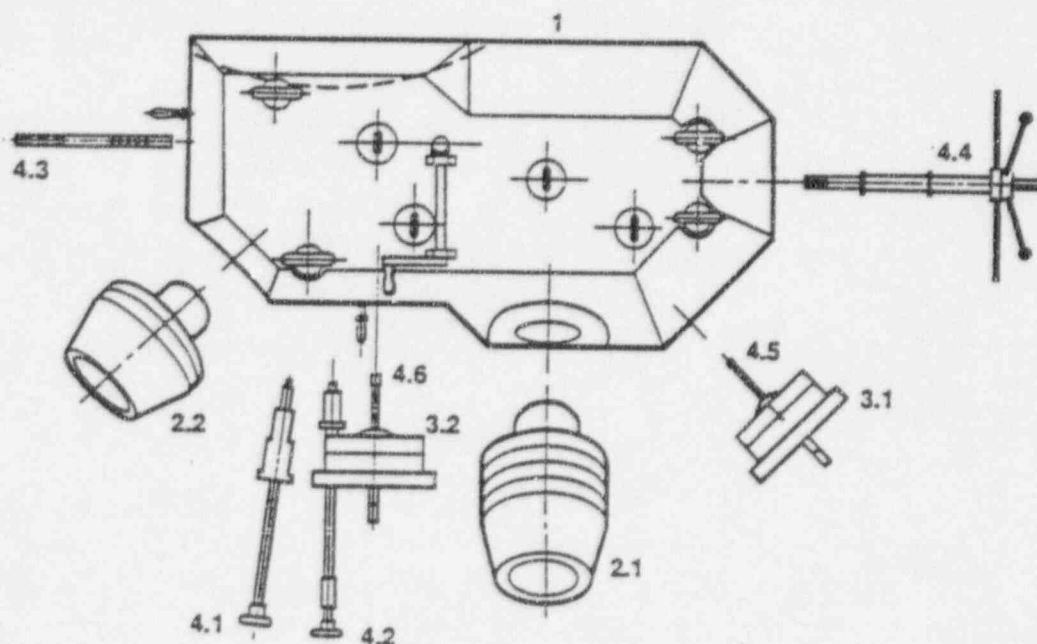


Fig. 2 Loading machine



Loader parts in the shipping container

- 1. Loading machine - main body
- 2.1 Window - unit, Cask cell
- 2.2 Window unit, Loading cell
- 3.1 Rotul - ball unit, Cask cell
- 3.2 Rotul - ball unit, Loading cell
- 4.1 Plug operating rod
- 4.2 Source loading rod
- 4.3 Separate source rod
- 4.4 Cask lid winch unit
- 4.5 Tong - Cask cell
- 4.6 Tong - Loading cell

In addition, the cask installation frame, the cask radiation shield and auxiliary equipment for erection are included in the container.

Fig. 3 Loading machine - dismantled for transportation

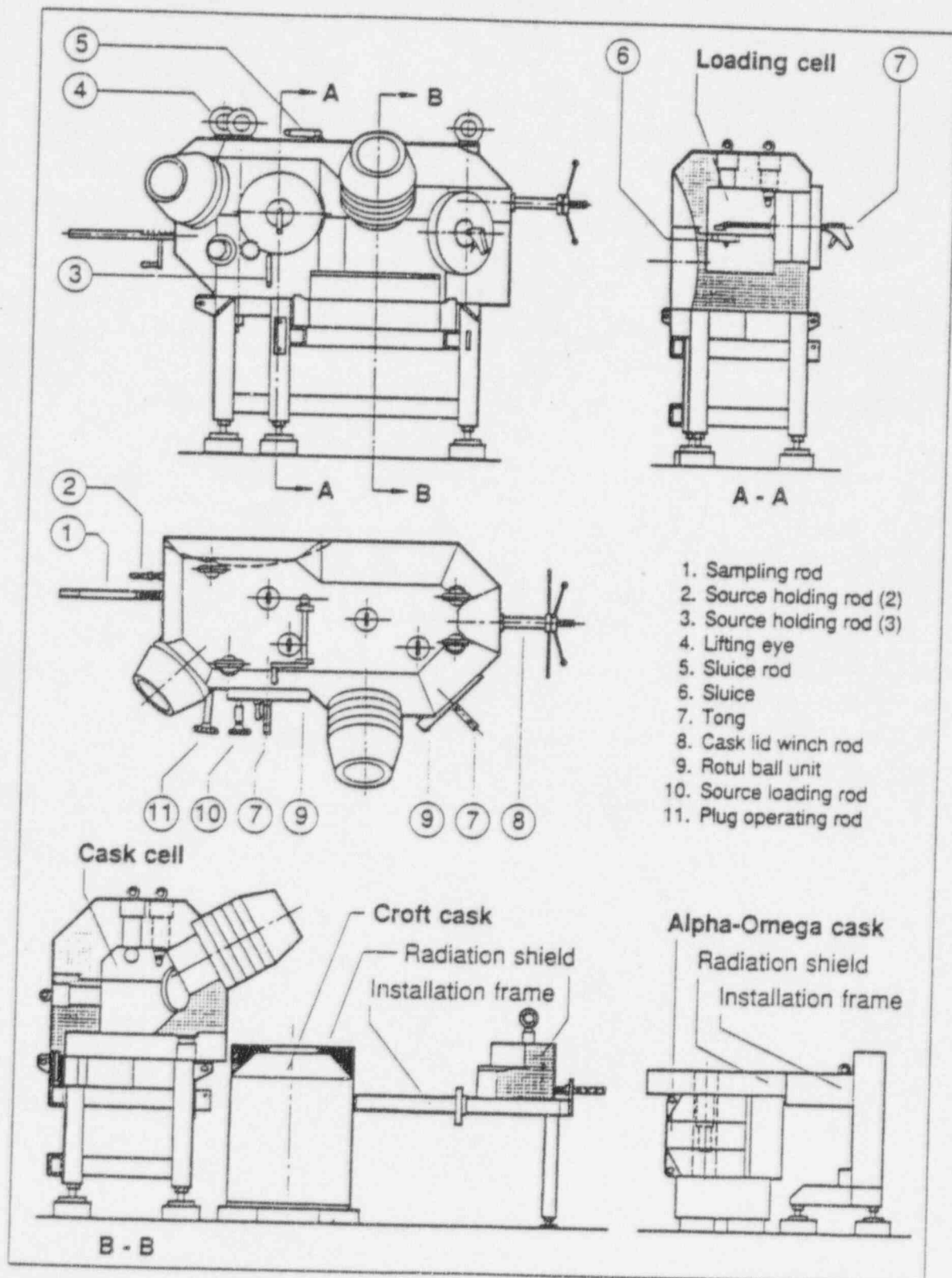


Fig.4. The assembled loading machine with installation frames for two different cask types

A3. Loading the Sources

The cask is guided and lifted to its stationary position in its cell in the machine frame - Fig. 4 - after docking the machine to the radiation unit - Fig. 5. A loading diagram must be used for transferring sources from the cask into the radiation unit through five loading channels in the radiation shield - Fig. 13.

The actual beam channel at the radiation unit must be aligned with the source loading rod of the loading machine by turning the radiation unit - Fig. 5 and 10.

A handwheel located in the indicator opening - Fig. 6 - is used to rotate the source body inside the radiation unit and each of the beam channels is aligned, one at a time, with its corresponding loading channel. When each source seating is correctly positioned for source loading, the source body is locked in-place by inserting a pin through the indicator ring. The actual source is inserted.

When the loading operation is completed, the source body is locked in its fixed position with locking pins. The five loading channels are sealed in the shield with the plugs provided for this purpose by using of the plug operating rod. A cover is spot-welded over the plugs. Finally, the shielding plug is inserted in the opening for the indicator.

A4. Unloading the Sources

After a certain time, reloading is necessary. The actual utilization period is determined by the treatment time that is most convenient to the patient.

To unload the sources, all electrical connections are disconnected and the radiation unit disengaged from the operating table. The loading machine is setup with an empty cask inside it and then docked to the radiation unit. All used sources are transferred to the cask, one by one. Unloading is performed in the same way as loading, but in the reverse order: see sections A3 and C.

The cask containing used sources should be transported to a recovery plant.

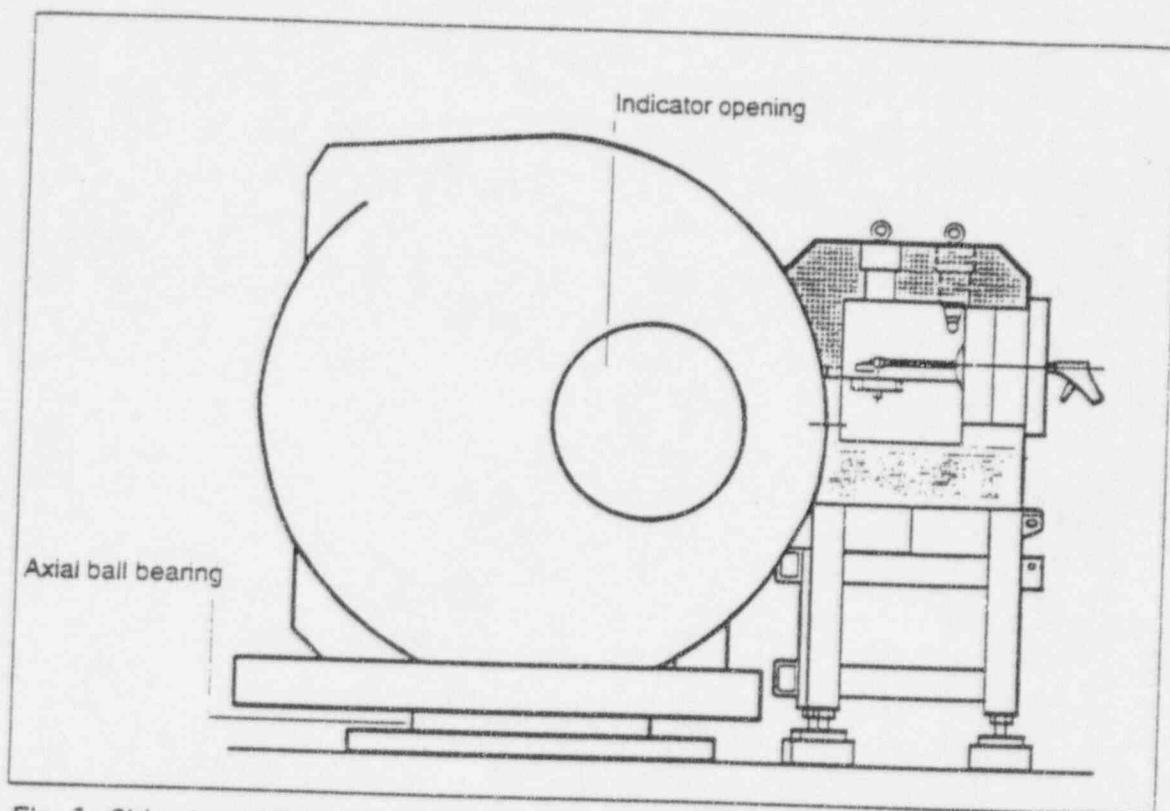


Fig. 5. Side view of the loading machine

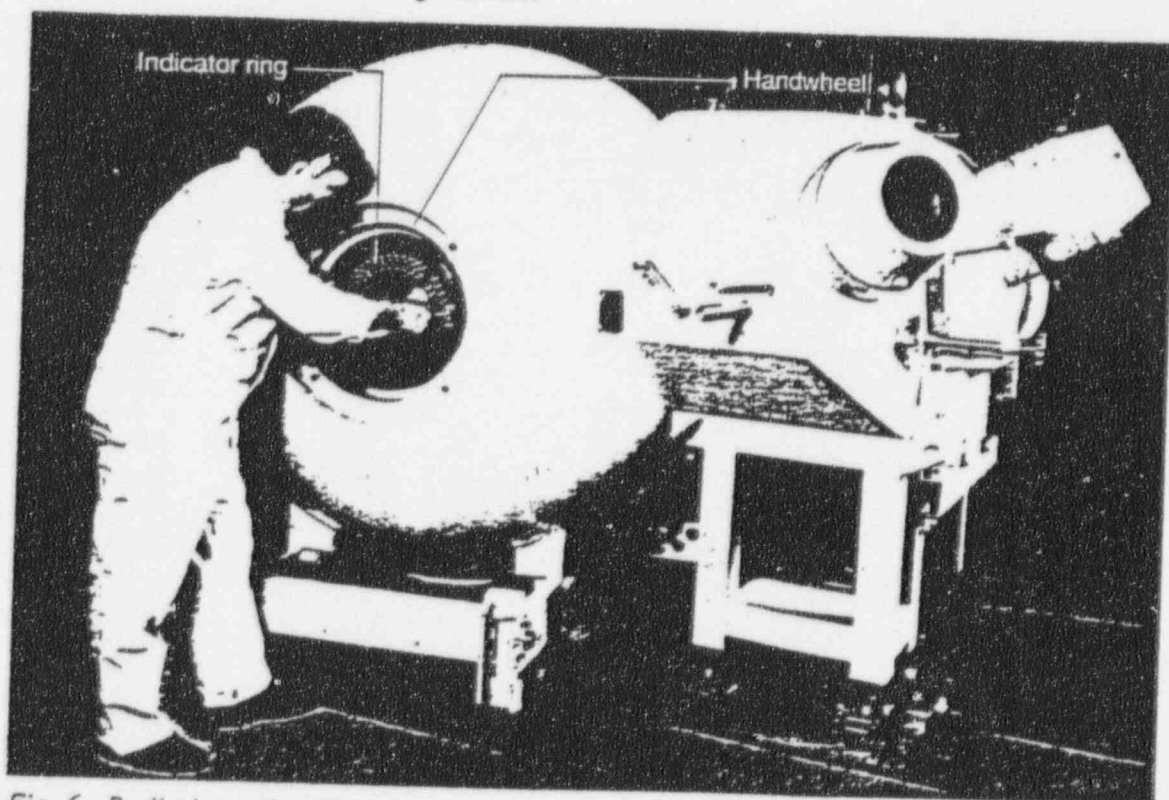


Fig. 6. Radiation unit with indicator ring and handwheel for rotating the source body

B. Assembling the Loading Machine and docking the Radiation Unit

B1. Assembling the Loading Machine

The loading machine, which is a shielded cell, is delivered in a dismantled state. As mentioned under A1, it is shipped in three transport cases in addition to the main body of the machine, the cask installation frame and its radiation shield. All parts must be handled with care e.g. to avoid deforming the lead components. The main body will be placed on roller blocks for installation in the right place in the loading room. In order to lock the movement of the body, it is recommended that each block be turned at an angle from the other blocks before mounting the separate components and docking the radiation unit.

The components to be assembled are shown in Fig. 3. Four lifting eye bolts - combining screws and nuts holding the top and bottom parts of the frame together - are positioned on top of the frame - Fig. 4. The assembly procedure is summarized below.

The two window units are first mounted, followed by the two Rotul ball units with the two tongs mounted. Finally, the cask lid winch rod, the Plug operating rod, the Loading rod and the Sampling rod are mounted. Special tools are available for mounting the two Rotul ball units and the window units. On top of the main body are two lighting plugs for the cask and loading cells installed via a transformer which must be connected to the mains supply.

B2. Docking the Radiation Unit

The radiation unit is placed on a transport frame with an axial ball bearing making it easily rotated. If the unit has been loaded before, the spot-welded covers over the five loading plugs in the shield of the radiation unit must first be loosened. After loosening the five plugs, but leaving them in place, the unit is placed against the surface of the main body of the loading machine. If necessary, the levelling devices must be adjusted - Fig. 5. After adjusting the radiation unit, by easy manual rotation, one of the five plugs can be removed from its hole by means of the plug operating rod and fixed there for the loading operation.

B3. Installing the Cask

The cask is lifted out of its transportation cover and placed on the cask frame - Alpha-Omegacask - and roller blocks, alternatively provided with the cask lid and placed on roller blocks - Croft cask - see Fig. 4. Using the cask installation frame, it is then guided into the loading machine and lifted into the operational position. The cask radiation shield will then be lifted and rolled into position outside the cask.

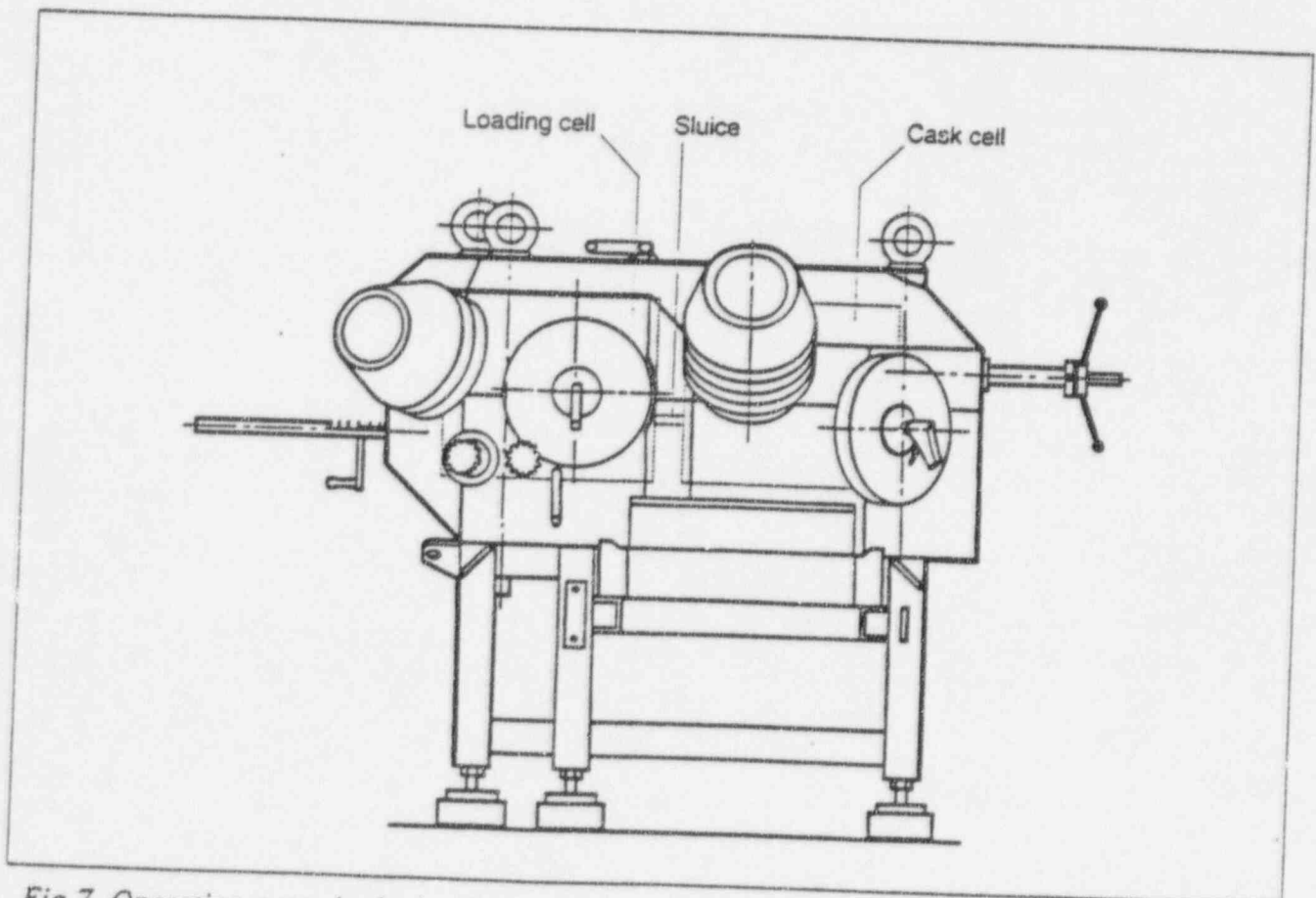


Fig.7. Operating areas in the loading machine - Cask cell and Loading cell

C. Loading Procedure

C1. Operating Inside the Cask Cell

The loading machine is docked to the radiation unit as described in section B2.

The cask plug is lifted into the cask cell with the cask lid winch - Fig. 8. The source holder rack is also lifted from the cask to the cask cell with a tool installed in a plug hole above the center of the cask. The rack must be lifted to a position where it is easy to grasp each of the sources on the plate and move them to the sluice by means of the tong.

The plate is then grasped with the tong, turned to the vertical position and hung on one of the two hooks on the cell wall. The rack is lifted one further step and further sources are moved. There is sufficient space on the hooks for all ten plates after moving all sources to the sluice.

Each source is numbered and must be inserted into the source body according to the loading diagram supplied by Elekta.

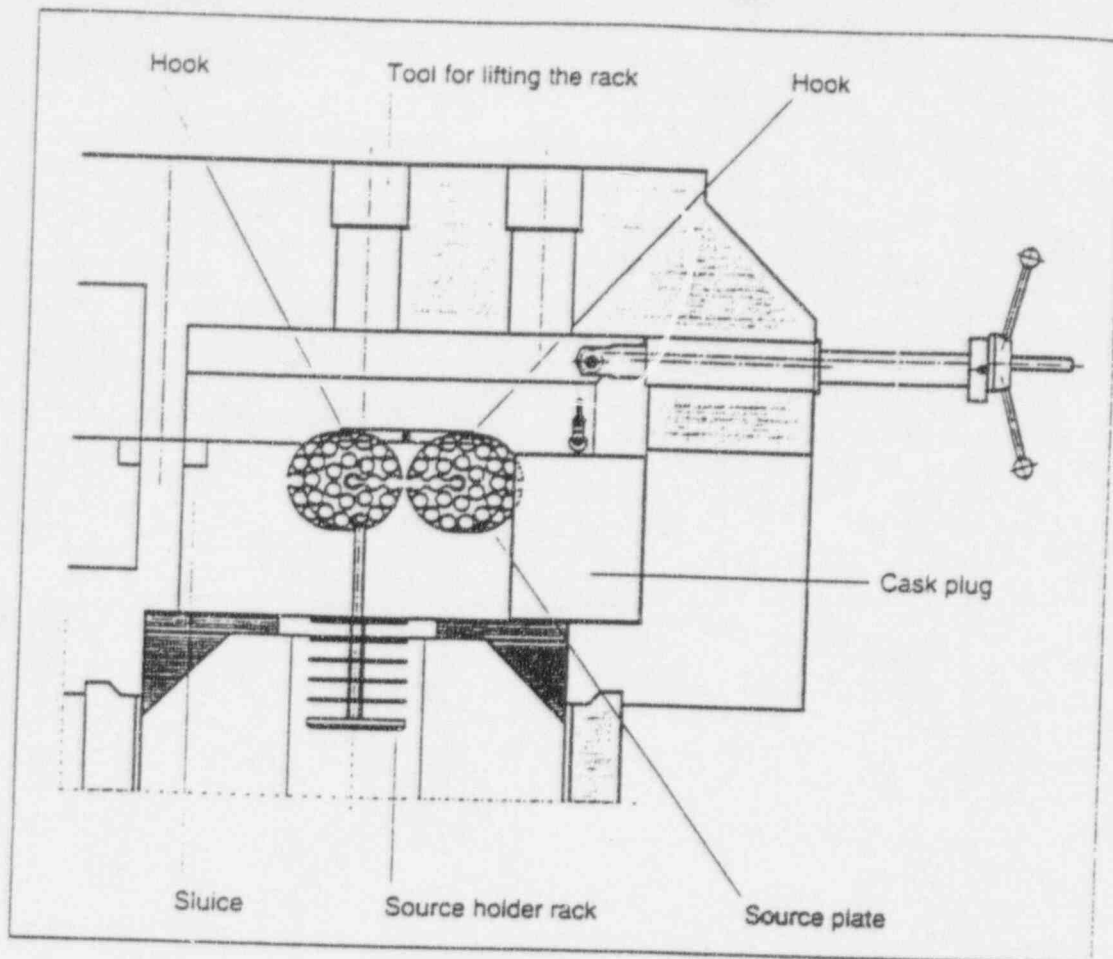


Fig. 8. Interior sketch: cask cell

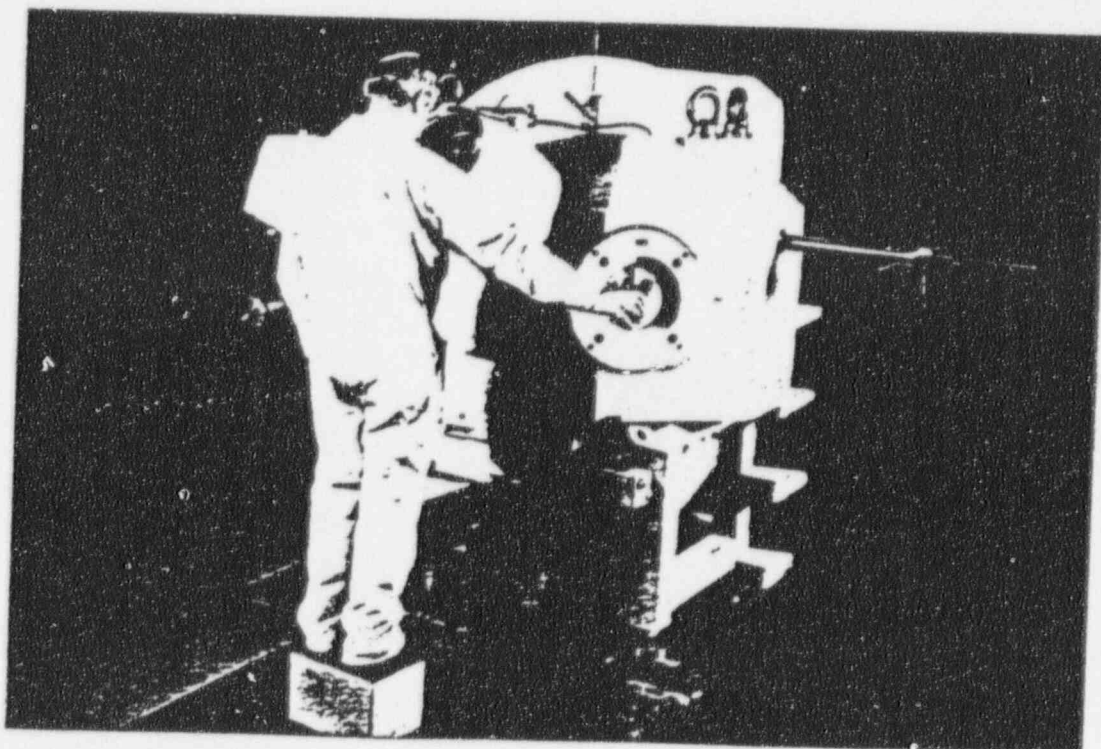


Fig. 9. Operating inside the cask cell

C2. Operating Inside the Loading Cell

After docking the radiation unit, this is turned with one of the plugs fitting the plug operation hole. By turning the plug operating rod in the plug thread, the plug is fixed to the rod - Fig. 4 and 10. It is then drawn into the loading cell and further turned in the thread of the plug operating rod bushing. When fixed, we recommend that the plug operating rod be drawn out of the loading machine as this makes it easier to operate with the source loading rod.

The radiation unit is then turned with the loading channel, now emptied from the plug, fitting the loading hole in the loading machine. With the hand-wheel attached to the indicator ring, the source body is rotated to the correct loading position according to the loading diagram.

The source is transferred to the loading cell by rotating the sluice handle - Fig. 4, 7, 8 and 10.

The source is gripped with the long tong in the loading cell and removed from the sluice. Using the handle (2), the source is then placed on the tipper receiver of source holding rod (2) in its horizontal position or on the source block and pushed into the tipper receiver of source holding rod (3) placed in its right position by means of the handle.

Note that the loading pattern must follow the loading diagram.

The handle of the source holding rod in question is used to turn the tipper receiver with the source in front of the loading channel. Using the source loading rod, the source is secured by turning the knob. After this operation, the rod must be withdrawn about 100 mm and the tipper returned to its horizontal - source rod (2) - or right - source rod (3) - position.

The loading rod carrying the source can now be pushed through the channel into the source body and the source be placed in its correct position as shown in the loading diagram. The source is released by unscrewing the knob and fully withdrawing the rod.

Loading continues by repositioning the source body of the radiation unit and also the sluice so that this faces the cask cell followed by loading all sources in the first plate in the same manner.

The first plate is then lifted away to free the next layer of sources and the rack assembly lifted to the next operating level. Loading continues as described above until one source row is full, after which it is plugged - see chapter C3. Loading continues with the next row of sources until the source body is completely loaded.

Sampling can also be performed with the aid of the sampling rod.

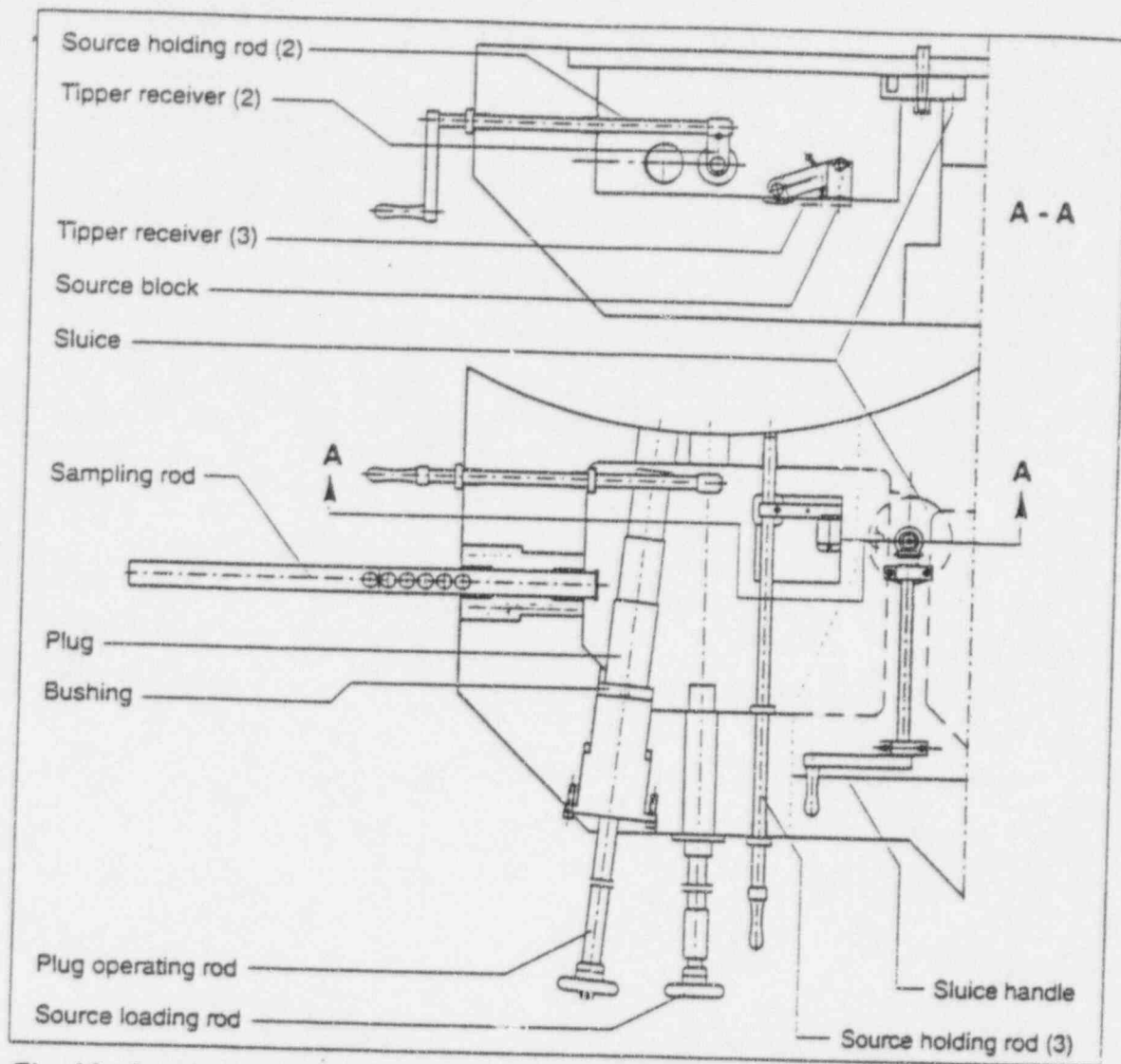


Fig. 10. Interior sketch: loading cell

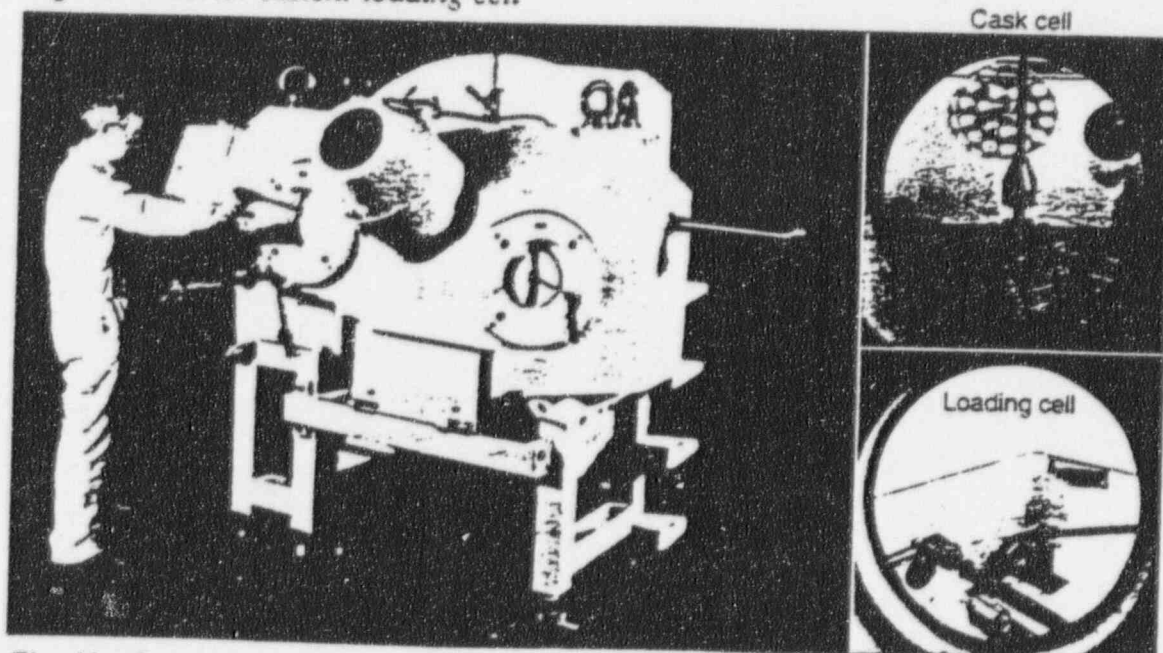


Fig. 11. Operating in the loading cell

Fig. 12. Interior views of the loading machine

C3. Completion of the Loading Procedure

When one row of sources is in place, the loading channel must be plugged. The radiation unit must then be turned with the loading channel fitting the hole for the plug operating rod - Fig. 10. The plug is pushed into the loading channel by means of the plug operating rod and tightened.

The plug operating rod is thereafter loosened and the radiation unit turned with the next loading channel fitting the hole for the plug operating rod. The plug is dismantled and drawn into the loader. The radiation unit is then turned again with the loading channel fitting the hole for the source loading rod - Fig. 10 - and the operations are continued until all sources are mounted.

All plates must be reassembled in their positions on the cask rack - Fig. 8. The rack is sunk to its position in the cask. The cask plug must be moved to a position above the cask and lowered to its closing position. The hook on the chain of the cask lid winch rod is removed.

The loading procedure is now complete. The radiation unit must be undocked from the loading machine to a distance of about 300 mm. The source body is locked to the central body with locking pins - Fig. 13.

Finally, the shielding plug is mounted in the opening for the indicator and shielding plugs inserted in the locking pin openings. The radiation shielding must be completed by spot-welding a cover over the loading channels on the radiation unit.

The loading team confirms the loading pattern by signing the loading diagram and storing it with the final customer documentation.

D. Dismantling the Loading Machine

When dismantling the loading machine, each part must be placed in its transport case. The dismantling procedure is the reverse of the assembly procedure.

To remove the cask, the radiation shield of the frame must be removed. The cask must be placed in its transport case.

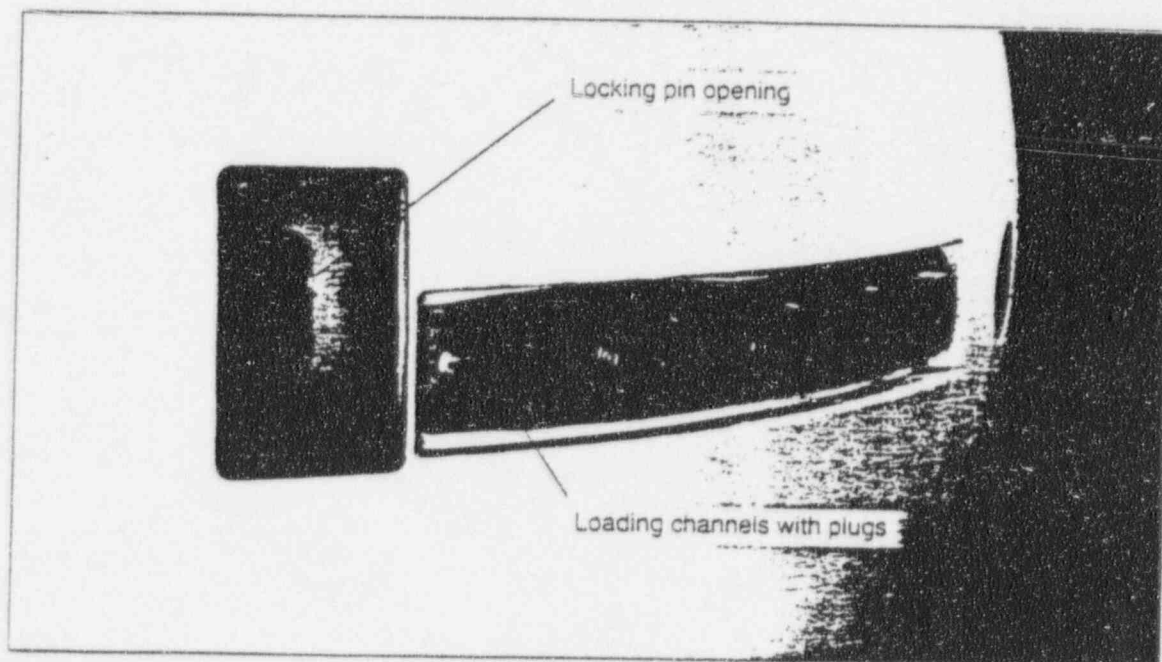


Fig. 13. Loading channels on the radiation unit

E. Radiation Exposure Rates

E1. Radiation Exposure Rates during Loading

In all normal working areas, radiation exposure is generally about 1 mR/h. Fig. 14 shows certain areas where radiation is higher.

These are:

- A. Around the loading machine, 5 mR/h.
- B. Above and around the cask, less than 10 mR/h.
- C. At the indicator ring of the radiation unit, 50 mR/h.
- D. At the shielding doors of the radiation unit 10 mR/h.

The radiation at the indicator ring on the rear of the radiation unit will increase after each loading of a radiation source until a maximum level of about 50 mR/h is reached. When all sources have been loaded, the indicator opening is sealed with a shielding plug. The leakage is then very low, having a maximum of 10 mR/h at the shielding doors.

E2. Radiation Leakage after Loading

When the loading operation is complete, and the sealing plugs mounted in the radiation unit, leakage is measured according to the NCRP 33 regulations. Measuring points are 1 m from the source; see Fig. 15.

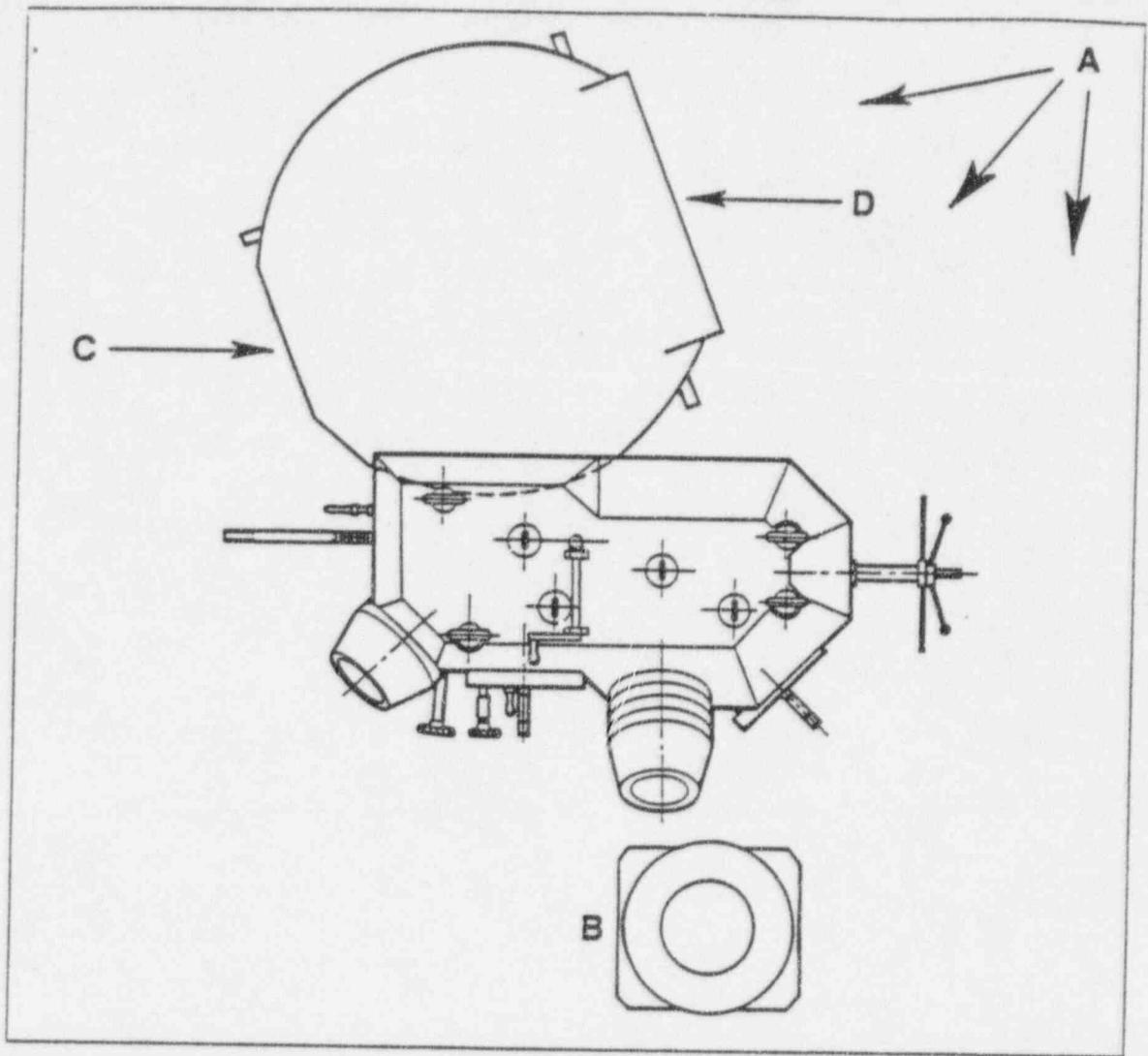


Fig. 14. Radiation exposure rates

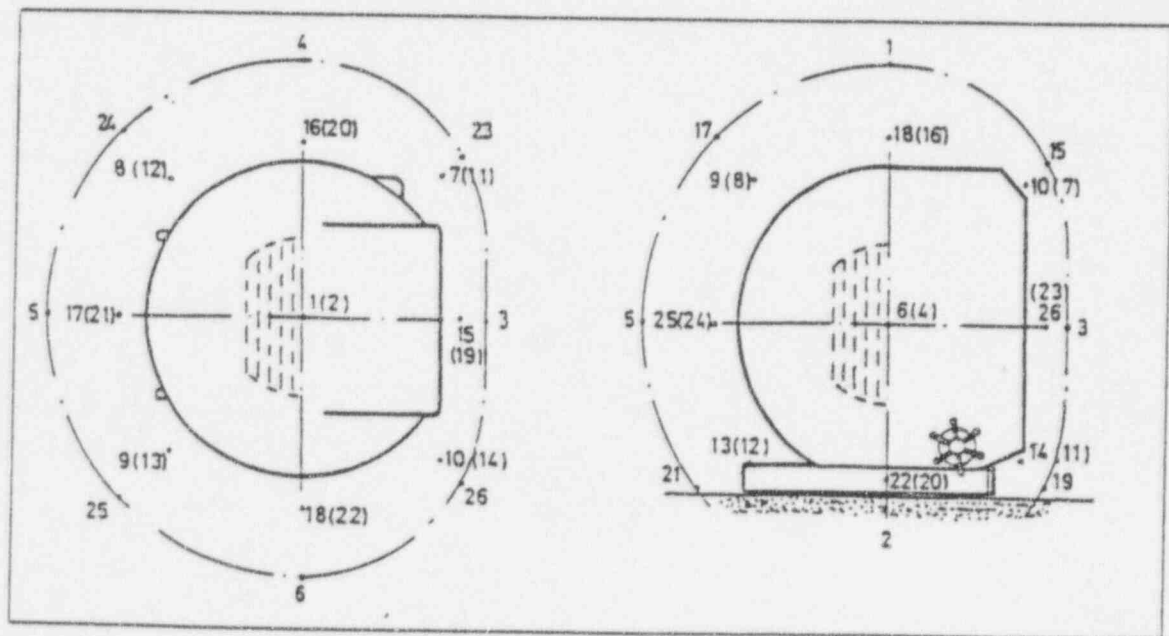
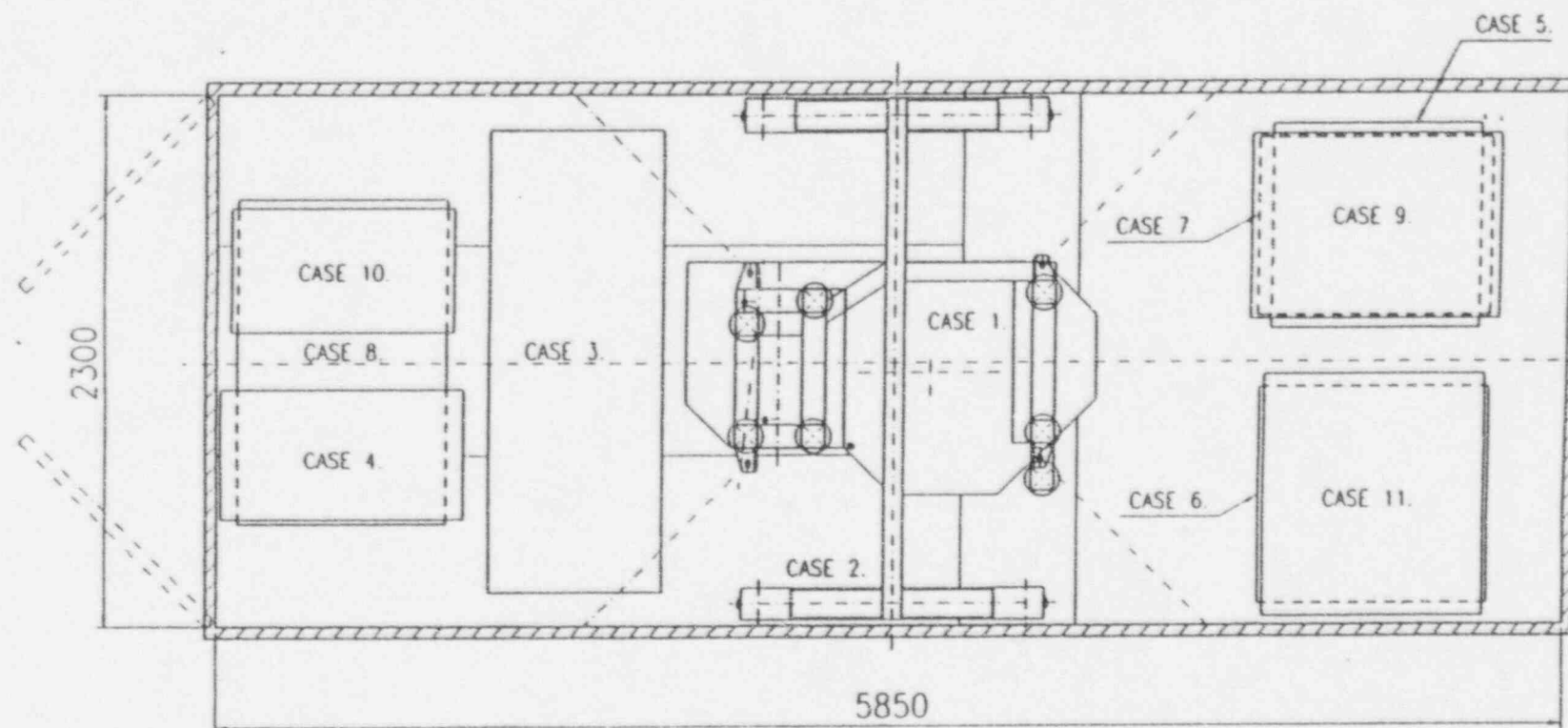


Fig. 15. Leakage measuring points according to NCRP 33

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WRITTEN CONSENT OF ELEKTA

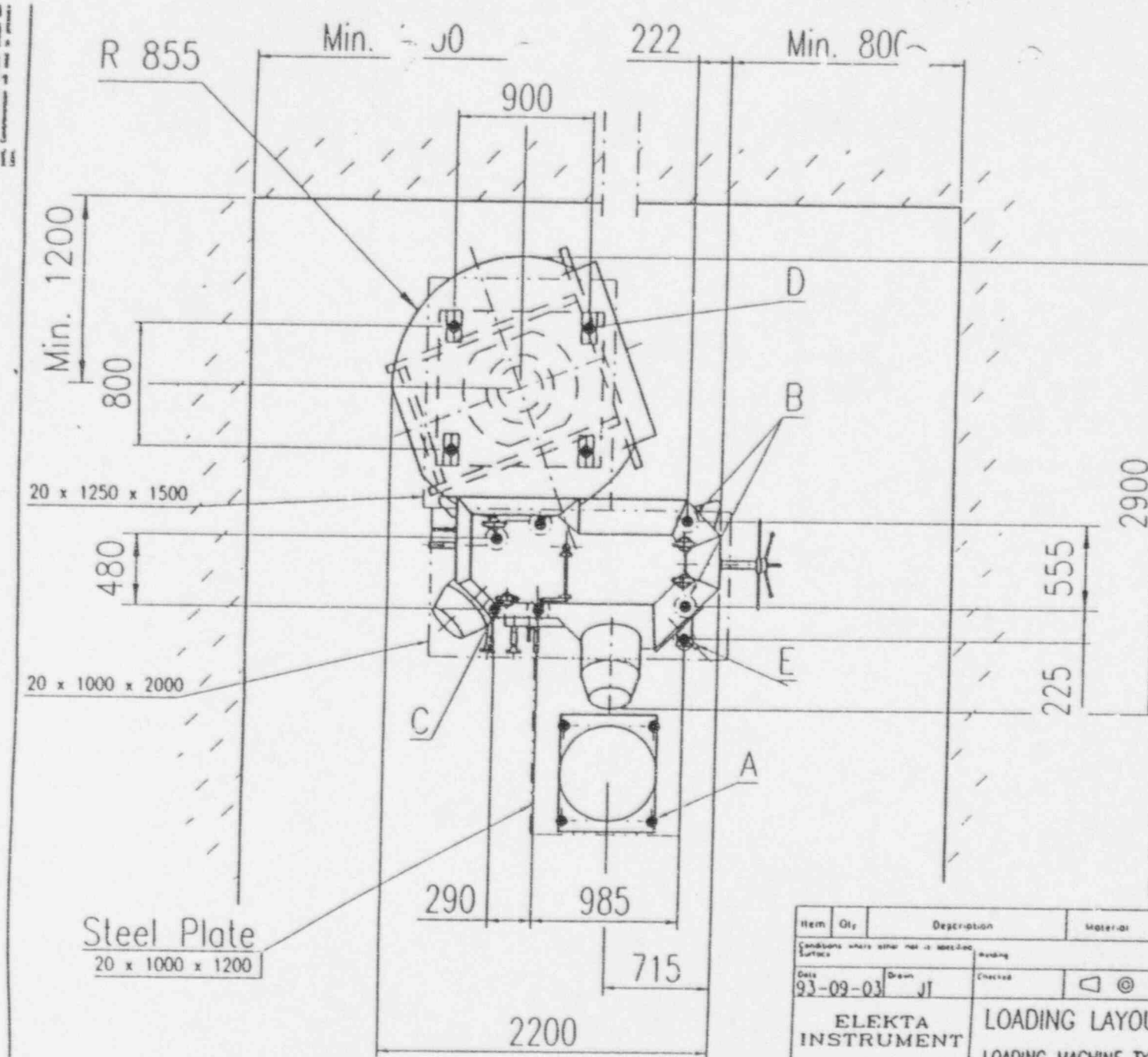
1 Case sizes changed 9404 JI



LGK TYPE B-LOADING MACHINE ROW/2

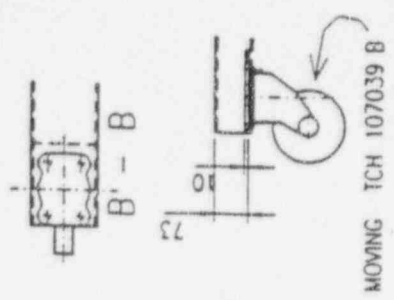
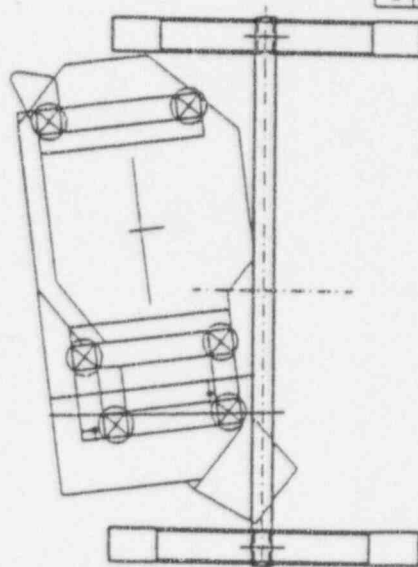
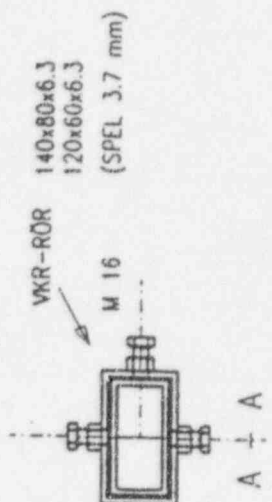
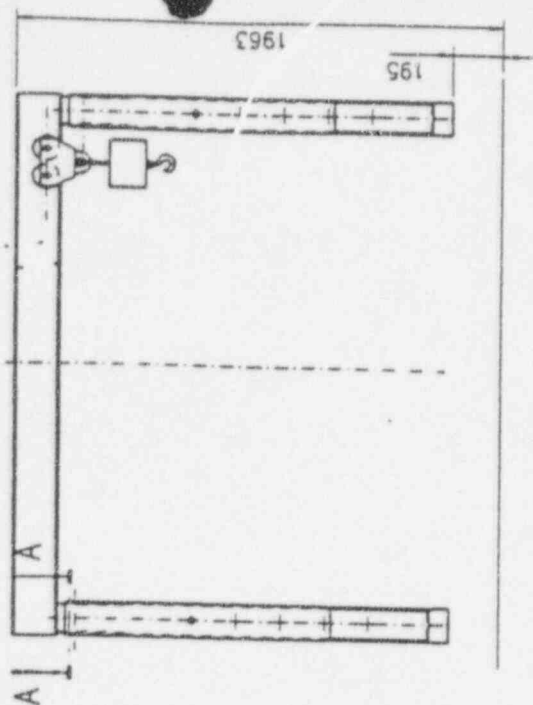
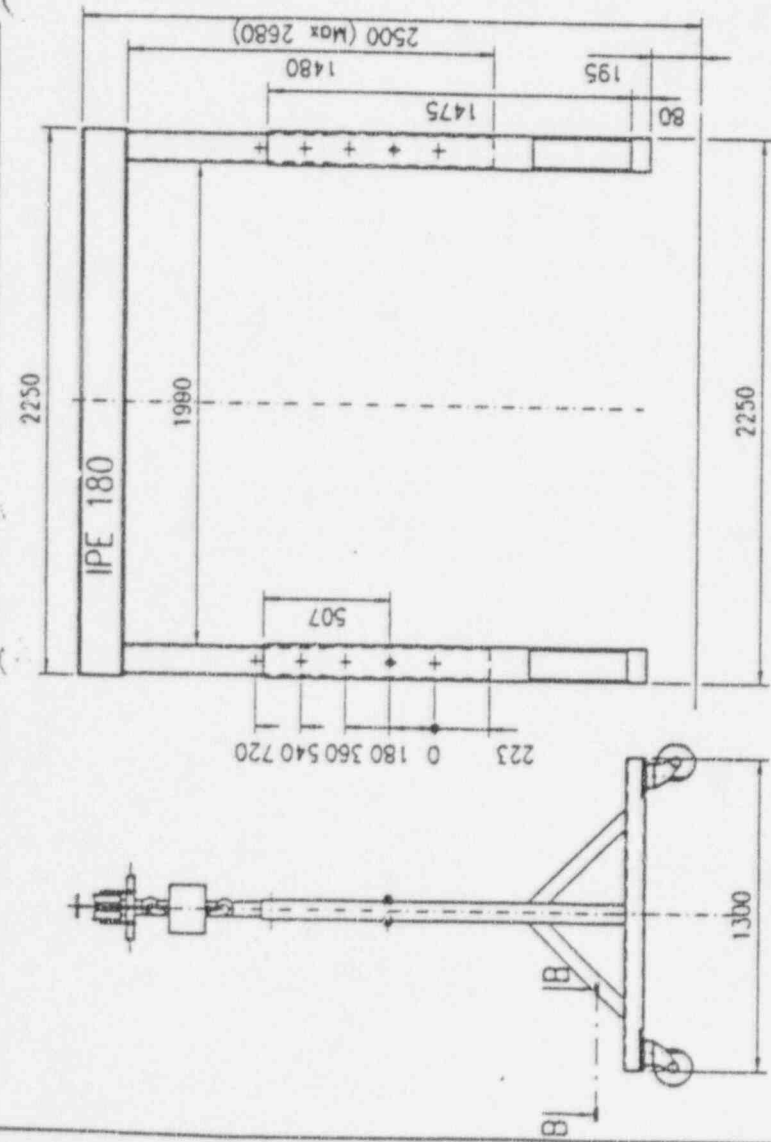
Item	Qty	Description	Material	Dimension, Article no	Weight kg
Conditions where other than as specified					
Date		Drawn	Checked	Scale	Notes
93-05-12		KES	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1:20	
ELEKTA INSTRUMENT		LOADING EQUIPMENT LOCATION IN CONTAINER			33853

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



- Loadpoint A = 1 ton (4x)
- Loadpoint B = 3 ton (2x)
- Loadpoint C = 2 ton (4x)
- Loadpoint D = 5 ton (4x)
- Loadpoint E = 0.5 ton

Item	Qty	Description	Material	Dimension	Article no	Weight kg
Conditions where other not is specified						
Date		Drawn	Checked	Scale	1:25	Ref
93-09-03		JT				
ELEKTA INSTRUMENT		LOADING LAYOUT				
		LOADING MACHINE TYPE B, Row/2				
		33862				



FOR ERRECTION OF LOADING MACHINE PARTS

Item	Qty	Description	Material	Dimension	Article no	Weight kg
<p>Comments: where stip not in spec line</p> <p>1.          </p>						
Drawn		Welding		Plate Steel 18815	Temp size	
Drill		Cracked		Size	Ref	
					Sheet	Cons
<p>ELEKTA INSTRUMENT</p> <p>PORTAL CRANE 10' 116 MACHINE ROW/2</p>						<p>430120 301708</p>

The Cleveland Clinic Foundation

Adequacy of Shielding - Gamma Knife Unit

1. All areas surrounding the Gamma Knife treatment room will be unrestricted areas.

2. a. Workload: A maximum of 10 patients per week with 6 isocenters per patient and each isocenter being treated for 30 minutes are the assumptions for determining the workload. This yields 30 hours of "beam on" time per week in the treatment (Rx) position. For each isocenter 2 minutes is allotted for the doors open but helmet not in treatment position, which yields 2 hours of "beam on" time for the withdrawn (Wd) position.

b. The parameters for the calculations are fixed for the treatment unit, the drawings provided are for the 18 mm helmet, no plugs and a phantom present for generating scatter. These are worst case assumptions. Standard concrete was utilized, 147 pounds/cubic foot, with HVL of 6.1 cm concrete and TVL of 20.3 cm concrete. For the door, as only scattered radiation is reaching this area, HVL and TVL values are for a 0.5 MV beam in accordance with recommendations from ICRP 33, Protection against Ionizing Radiation from External Sources used in Medicine, paragraphs 242 - 244. For lead this results in a HVL of 0.31 cm and a TVL of 1.03 cm. For the West wall and the western portions of the North and South walls this recommendation was also utilized with an HVL of 1.18 cm and a TVL of 11.9 cm for concrete.

c. Distribution of kerma rate drawings from Elekta, attached, were utilized to calculate the shielding requirements. For the orientation at this site, the East wall and portions of the ceiling and portions of the North and South walls were calculated as primary barriers. As there is no occupiable space under the unit, built on grade, no shielding calculations are presented for the floor. The diagrams from the vendor were used to determine the total dose for each calculation point with no corrections for scatter-to-primary or scatter angle applied.

d - g. All areas were shielded for 0.002 rem/week (20 μ Sv/week) and with an occupancy factor and use factor of 1.0. These assumptions coupled with the generous "beam-on" times used, preclude the possibility of exposures exceeding 0.002 rem (20 μ Sv) in any one hour. Calculations are on the attached spreadsheet. The "footprint" of the planned room has been superimposed on the kerma rate drawings to demonstrate dose rates used for calculations. Due to the range of values in each area, conservative estimates were chosen and are summarized below:

East wall - for treatment position (Rx) values were 500 -600 μ Sv/hour, 600 μ Sv/hr used for Rx dose rate; for withdrawn position (Wd) values were 400-1000 μ Sv/hr, 1000 μ Sv/hr was used for Wd dose rate.

South wall - as shown on the diagram a portion of this wall is struck by radiation scattered once and due to the range from 10 μ Sv/hour to 500 μ Sv/hour, three discrete sections were identified:

A - primary barrier, Rx ranged from 50 - 500 μ Sv/hour, used 500 μ Sv/hour for Rx; Wd ranged from 150 - 800 μ Sv/hour, used 800 μ Sv/hour for Wd.

Adequacy of Shielding

Page 2

B - primary barrier, Rx was 30 $\mu\text{Sv}/\text{hour}$ used 50, $\mu\text{Sv}/\text{hour}$ for Rx; Wd ranged from 70 - 100 $\mu\text{Sv}/\text{hour}$, used 150 $\mu\text{Sv}/\text{hour}$ for Wd.

C - scattered barrier, Rx was 10 - 20 $\mu\text{Sv}/\text{hour}$, used 20 $\mu\text{Sv}/\text{hour}$ for Rx; Wd ranged from 20 - 50 $\mu\text{Sv}/\text{hour}$ used 50 $\mu\text{Sv}/\text{hour}$. Used 0.5 MV TVL's.

Door - Rx used 10 $\mu\text{Sv}/\text{hour}$; Wd used 20 $\mu\text{Sv}/\text{hour}$. Used 0.5 MV TVL's.

West wall - wall is one meter beyond reported values of 40 $\mu\text{Sv}/\text{hour}$ for Rx and 60 $\mu\text{Sv}/\text{hour}$ for Wd. Used 0.5 MV TVL's.

North wall - As on South wall, three discrete areas were defined:

A - Rx values ranged from 20-30 $\mu\text{Sv}/\text{hour}$, used 30 $\mu\text{Sv}/\text{hour}$ for Rx; for Wd values ranged from 30 - 70 $\mu\text{Sv}/\text{hour}$, used 70 $\mu\text{Sv}/\text{hour}$. Used 0.5 MV TVL's.

B - primary barrier, Wd ranged from 30 - 100 $\mu\text{Sv}/\text{hour}$, used 100 $\mu\text{Sv}/\text{hour}$; for Wd values ranged from 70 - 200 $\mu\text{Sv}/\text{hour}$, used 200 $\mu\text{Sv}/\text{hour}$.

C - primary barrier, Wd ranged from 100 - 800 $\mu\text{Sv}/\text{hour}$, used 800 $\mu\text{Sv}/\text{hour}$; for Wd values ranged from 200 - 1200 $\mu\text{Sv}/\text{hour}$, used 1200 $\mu\text{Sv}/\text{hour}$.

Ceiling - As with North and South wall, three discrete sections were identified:

A - primary barrier, Rx ranged from 100 - 800 $\mu\text{Sv}/\text{hour}$, used 800 $\mu\text{Sv}/\text{hour}$; for Wd values ranged from 200 - 1200 $\mu\text{Sv}/\text{hour}$, used 1200 $\mu\text{Sv}/\text{hour}$.

B - primary barrier, Rx ranged from 30 - 100 $\mu\text{Sv}/\text{hour}$, used 100 $\mu\text{Sv}/\text{hour}$; for Wd values ranged from 70 - 200 $\mu\text{Sv}/\text{hour}$, used 200 $\mu\text{Sv}/\text{hour}$.

C - Rx ranged from 10 - 30 $\mu\text{Sv}/\text{hour}$, used 30 $\mu\text{Sv}/\text{hour}$; for Wd values ranged from 30 - 70 $\mu\text{Sv}/\text{hour}$, used 70 $\mu\text{Sv}/\text{hour}$. Used 0.5 MV TVL's.

Leakage radiation rates, see attached Measured Leakage Radiation that has penetrated the external shielding of the idle treatment unit from Elekta, are well below 20 $\mu\text{Sv}/\text{hr}$ around the unit with the exclusion of measurement point 3. For the designed distances to occupiable areas outside the treatment room and for shielding determinations for primary and scatter, no additional shielding is required for leakage radiation when the unit is in the "beam-off" mode to ensure compliance with unrestricted area exposure rate limits.

During loading of the sources, see attached Dose rate during loading from Elekta, indicated dose rates are adequately shielded by primary and scatter calculations. No additional shielding is required for dose rates that will be present during the loading. The RSO will be present during the loading to ensure dose rates in surrounding areas are within acceptable limits.

3. From shielding information presented, dose rates in adjoining areas will be less than 20 μSv in any one hour and less than 1000 $\mu\text{Sv}/\text{year}$. Surveys to confirm these calculations will be performed following the loading of the sources in accordance with 10 CFR 35.641.

4. The treatment room is the only restricted area and this is only during treatment. The operator will have the responsibility for ensuring only the patient is in the room prior to initiating treatment. The operator of the unit will be responsible for ensuring personnel in the area have whole body dosimeters if they are part of the GSR team in the event an unusual occurrence should transpire. Badges will be issued to members of the GSR team following completion of appropriate training. A "Caution, High Radiation Area" sign will be on the door to the treatment room and during treatments, a warning light will be illuminated above the door to the treatment room. The treatment room door will be under continuous observation by the operator of the unit during use and the door is interlocked to discontinue treatment if opened during treatment. Surveys around the unit in the non-treatment mode will be performed by the RSO following source loading in accordance with 10 CFR 35.641.

$1\mu Sv = 0.1 mrem$

ELEKTA

Distribution of air kerma rate ($\mu Sv h^{-1}$) in the treatment room of the Elekta Gamma Knife model B.

It is assumed that the radiation unit is loaded with an activity of 2.2×10^{14} Bq. The values are given at 1 m above the floor level, the shielding doors of the radiation unit are fully open and the 18 mm helmet is in treatment position. Note. The purpose with this layout is to provide data for the dimensioning radiation shielding of the treatment room. The values should for the purpose of shielding dimensioning be regarded as primary ^{60}Co -radiation except for the shadowed areas where in some situations the contribution of scattered radiation may be considered. Scale: Matrix density 100 cm.

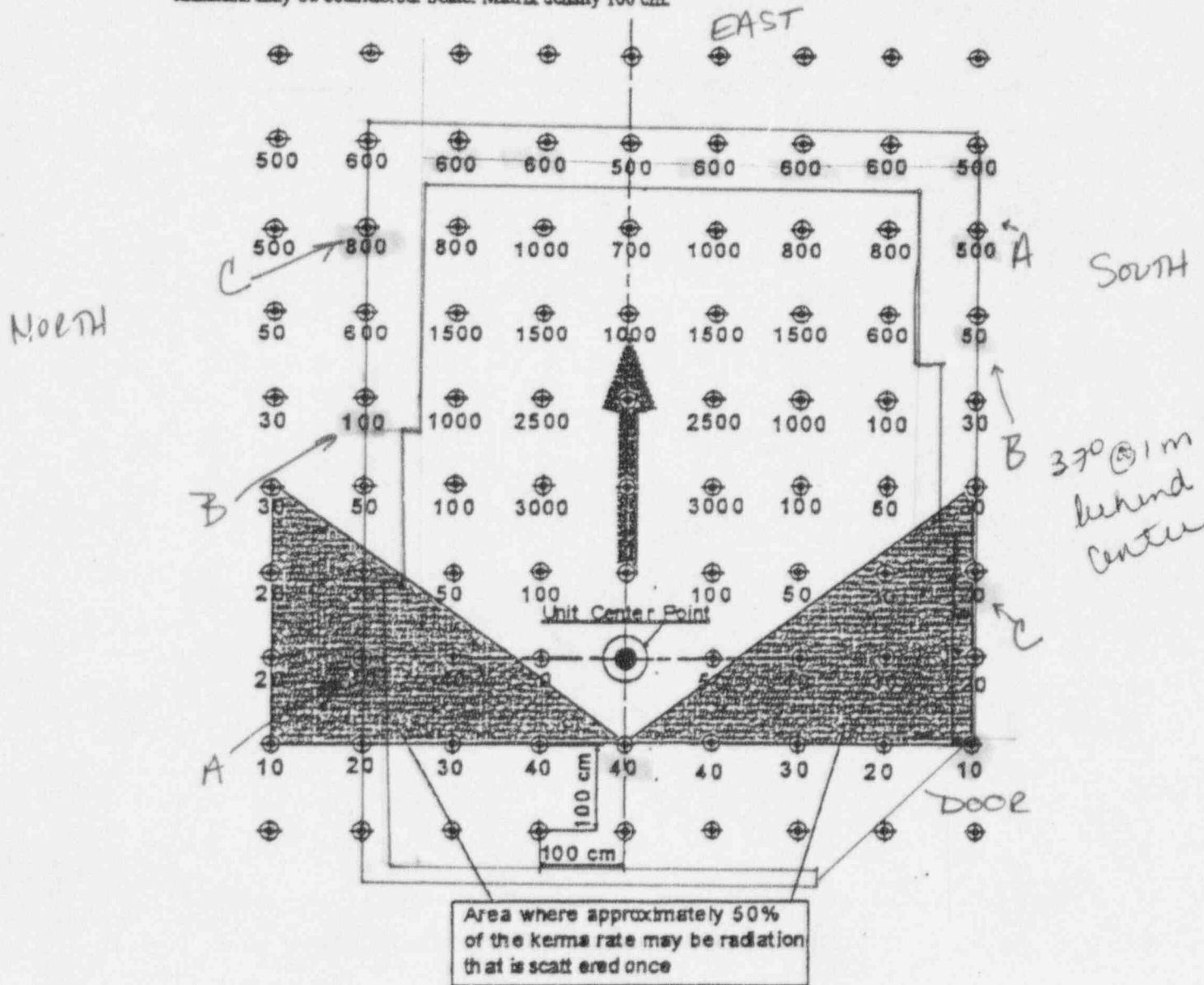


FIGURE 1

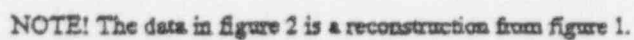
ELEKTA INSTRUMENT LAB, BOX 7593, S-18393 STOCKHOLM, TELEFON 08-402 54 00, FAX 08-402 5500

Thicknesses
Approximate

WEST

DRAWING 43818

ELEKTA



DRAWING 43818A

ELEKTA

Distribution of air kerma rate ($\mu\text{Sv h}^{-1}$) in the treatment room of the Elekta Gamma Knife model B.

It is assumed that the radiation unit is loaded with an activity of 2.2×10^{14} Bq. The values are given at 1 m above the floor level, the shielding doors of the radiation unit are fully open and the 18 mm helmet is in withdrawn position. Note. The purpose with this layout is to provide data for the dimensioning radiation shielding of the treatment room. The values should for the purpose of thickening dimensioning be regarded as primary ^{60}Co -radiation except for the shadowed areas where in some situations the contribution of scattered radiation may be considered. Scale: Matrix density 100 cm.

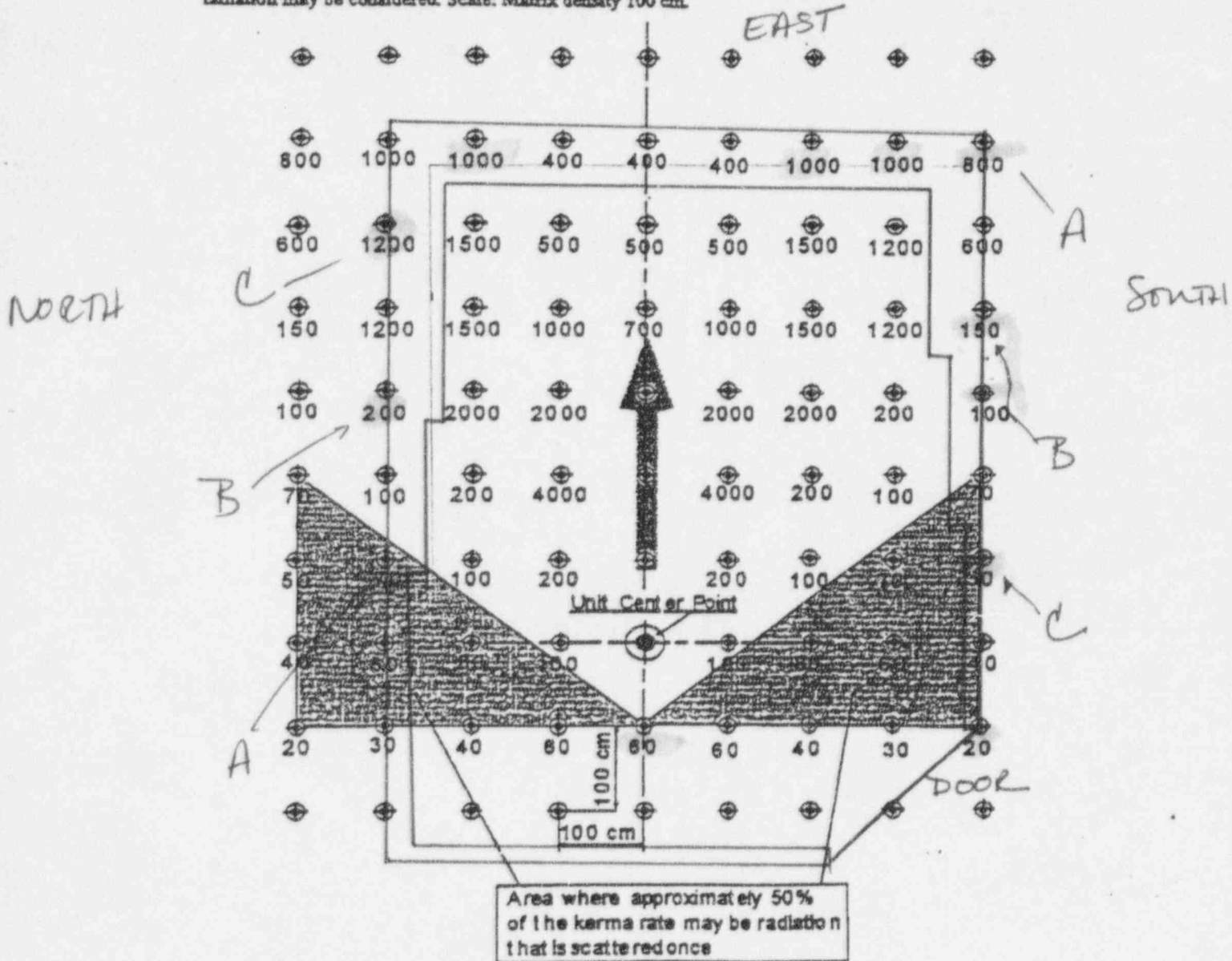


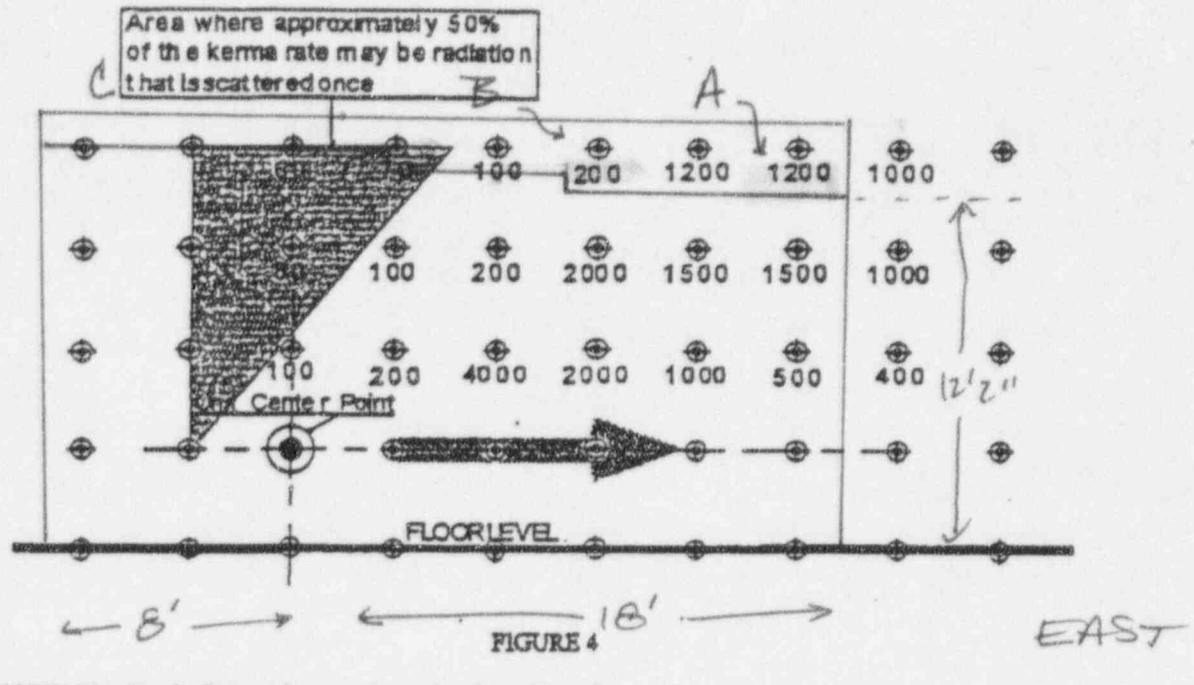
FIGURE 3

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DRAWING 43819

withdrawn
position

ELEKTA



NOTE! The data in figure 4 is a reconstruction from figure 3.

Gamma Knife Shielding Recommendations

Location	Distance feet	Distance meters	Dose rate-Rx uSv/hour	Dose - Rx uSv	Dose rate-Wd uSv/hour	Dose - Wd uSv	Total dose	Trans. factor	# TVL's	Calculated barrier	Recommended barrier
East wall	18	5.5	600	18000	1000	2000	20000	1.00E-03	3.0	24"	24"
South wall											
A	12.25	3.7	500	15000	800	1600	16600	1.20E-03	2.92	23.3"	24"
B	12.25	3.7	50	1500	150	300	1800	1.10E-02	1.95	15.6"	18"
C	12.25	3.7	20	600	50	100	700	2.90E-02	1.54	7.2"	9"
Door	13 @45	3.96	10	300	20	40	340	5.90E-02	1.23	0.5" Pb	0.5" Pb
West wall	8	2.44	<40	1200	<60	120	1320	1.50E-02	1.82	8.5"	9"
North wall											
A	8	2.44	30	900	70	140	1040	1.90E-02	1.72	8"	9"
B	8	2.44	100	3000	200	400	3400	5.90E-03	2.23	17.8"	18"
C	8	2.44	800	24000	1200	2400	26400	7.60E-04	3.12	24.9"	27"
Ceiling											
A	12.17	3.71	800	24000	1200	2400	26400	7.60E-04	3.12	24.9"	25"
B	12.17	3.71	100	3000	200	400	3400	5.90E-03	2.23	17.8"	18"
C	12.17	3.71	30	900	70	140	1040	1.90E-02	1.72	8"	9"

MEASURED LEAKAGE RADIATION THAT HAS PENETRATED THE EXTERNAL SHIELDING OF THE IDLE TREATMENT UNIT

Material

Survey meter model: Scitomat 6134A. (Automess. d-6802 Ladenburg) No. 67650.
 Calibrated: Oct. 1993 at Bundesamt für Hoch- und Vermessungswesen, Wien, Austria.
 Gamma Knife #30B. Universitäts Klinik, Graz, Austria.
 Total activity of all 201 ^{60}Co -sources: 236.6 Tbq (6395 Ci) Calibrated: Feb. 1, 1992.
 Date of measurement: October 1993

Method

All measurements have been made with the shielding doors of the Gamma Knife closed. The figures given in the table below are measurements of radiation that is emitted by the sources and that is transmitted through the external shielding of the Gamma Knife.

The data has been measured at a distance of 60cm from the outer surface of the unit which corresponds approximately to a distance of 100cm from the closest source. The location of the measurement points are selected in accordance with those recommended in NCRP33, see drawing 43834.

Result

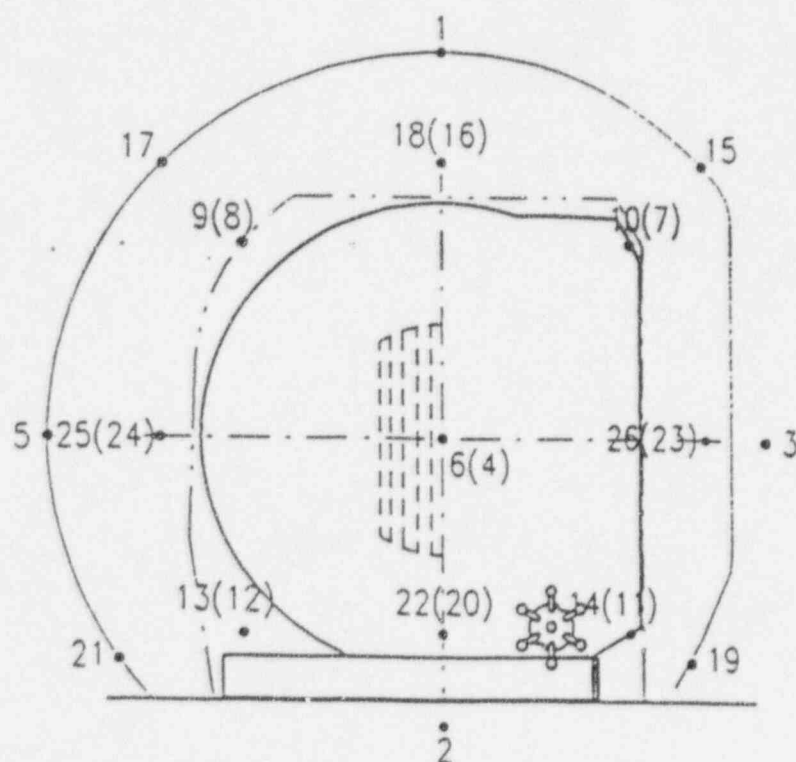
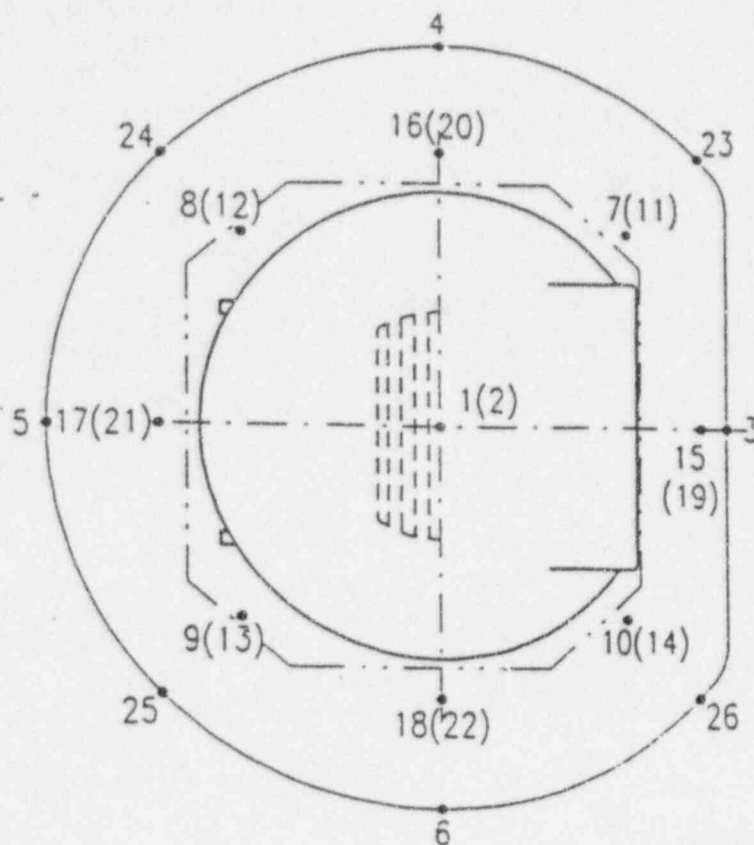
Note: The measurements are given in air kerma rate ($\mu\text{Sv h}^{-1}$), $10 \mu\text{Sv h}^{-1} = 1\text{mR h}^{-1}$. Values in brackets are measured data recalculated for a source activity of 244 Tbq (6600 Ci). All tabulated values are averaged from two measurements.

Measurement Point	Air kerma rate ($\mu\text{Sv h}^{-1}$)	Measurement Point	Air kerma rate ($\mu\text{Sv h}^{-1}$)
1	5.25 (6.7)	14	4.5 (5.7)
2	*	15	1.3 (1.6)
3	20.0 (27.8)	16	5.75 (7.4)
4	4.85 (6.2)	17	8.4 (10.6)
5	0.7 (0.9)	18	5.0 (6.4)
6	5.0 (6.4)	19	4.25 (5.4)
7	1.5 (1.9)	20	5.0 (6.4)
8	6.5 (8.4)	21	1.85 (2.3)
9	5.5 (7.1) **	22	4.25 (5.4)
10	1.45 (1.9)	23	2.5 (3.2)
11	5.8 (7.4)	24	8.85 (11.4)
12	7.0 (8.9)	25	8.5 (10.5)
13	4.6 (5.9)	26	2.4 (3.1)

* Measurement Point 2 not accessible.

** Measurement Point 9 at 58.5cm.

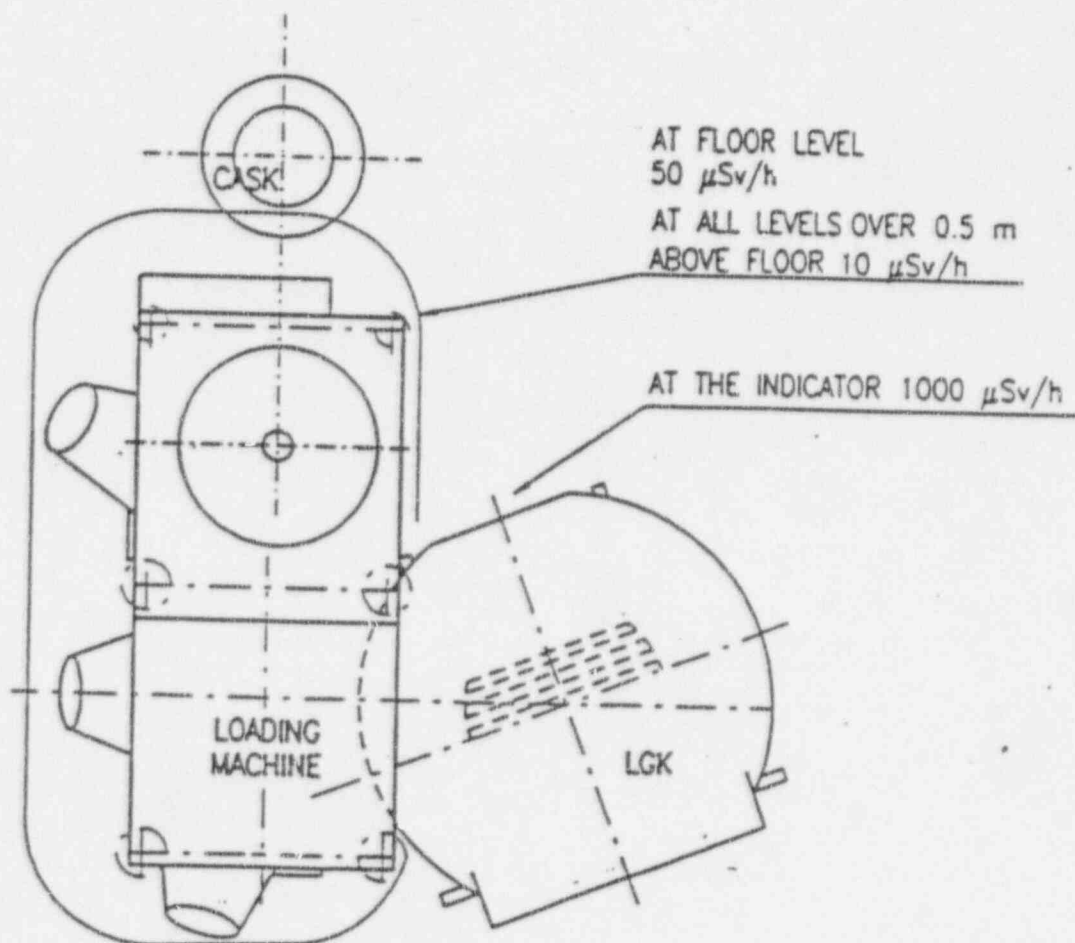
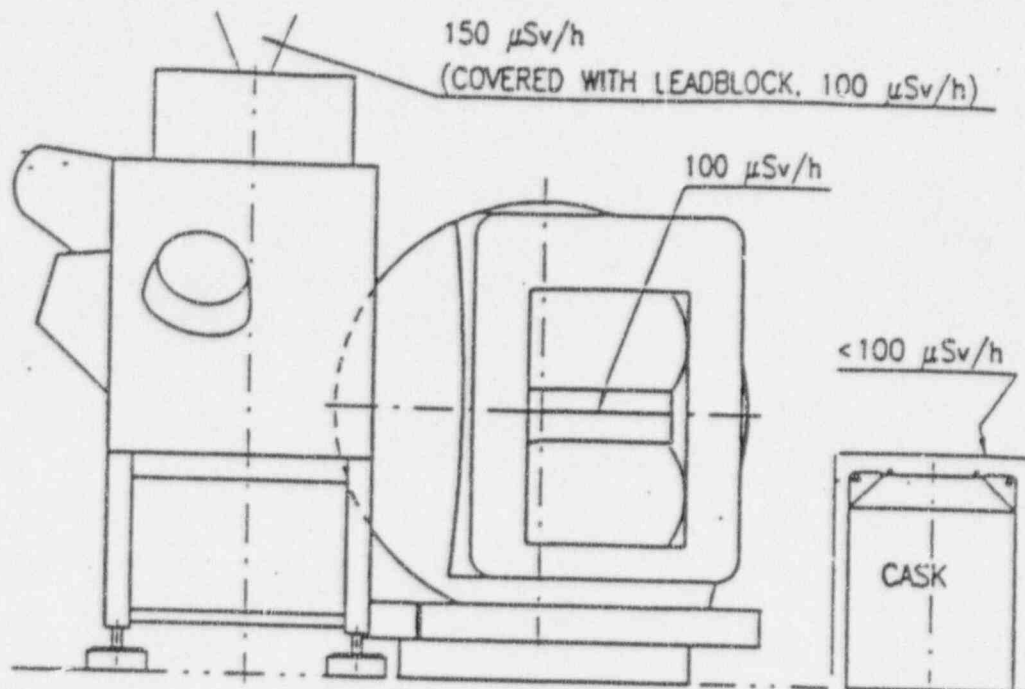
The area of the Gamma Knife where the highest air kerma rate is detected is not included in the 26 points of the table. This area is located at the lower part of the lower shielding door. There, at 5cm distance from the door surface a maximum of approximately $500 \mu\text{Sv h}^{-1}$ can be expected. At 60cm from the same surface the maximum reading will approximately be $50 \mu\text{Sv h}^{-1}$.



LEKSELL GAMMA KNIFE, type B (23004)
Measurement points according to NCRP 33

92-04-07

43834



Leksell Gamma Knife type B and
Loading Machine ROW in position for loading
Dose rate during loading.

92-05-12

43841

THE NORTHERN OHIO GAMMA-KNIFE CENTER

DRAFT

B-type Gamma Knife Emergency Procedures

A Power Failure During Treatment

- couch is automatically withdrawn from unit
- physicist assures that the shielding door has closed
 - if it has not, then the team shall remove all individuals from room, close the door and secure the area and call the radiation safety office (see posted call list)
- if power failure was momentary, treatment may be resumed (do not reset timers!)
- if power failure is extended, remove patient from fixation and consult with physicians and/or physicists and/or radiation safety office (see posted call list)

B Power Failure During Treatment & Failure of Couch to Withdraw

- team members as needed to enter treatment room (and to try to stay in scatter area)
- physicist and therapist and/or dosimetrist use emergency release rods to disengage patient
- physician and those finishing with the release rods to assist patient in departing the room
- physicist to close door, secure area
- call radiation safety office (see posted call list)

C Failure of Couch to Withdraw at End of Treatment

- operator to press emergency stop button
- if couch fails to withdraw, team opens door slightly (asserting interlock)
- if couch fails to withdraw, team to enter treatment room and try to stay in scatter area
- physicist and therapist and/or dosimetrist use emergency release rods to disengage patient
- physician and those finishing with the release rods to assist patient in departing the room
- physicist to close door, secure area
- call radiation safety office (see posted call list)

D Radiation Monitor Alarms Other than During Treatment Cycle

- physicist to immediately determine status of shielding door
 - if Gamma Knife shielding door is open, team shall remove all individuals from room, close door and secure area
 - call radiation safety office and then radiation oncology physics (see posted call list)
 - if Gamma Knife shielding door is closed, physicist and/or RSO shall use survey meter to measure the exposure level at the location of the room monitor (normally $< 0.1 \text{ mR/h}$) and in front of the shielding door at the rear of the helmet (normally $< 1 \text{ mR/h}$). If the measured values exceed expected values, team shall remove all individuals from the room, secure the area, call the radiation safety office and/or radiation oncology physics. Otherwise, if radiation exposure levels are normal, suspect malfunction of the area monitor. Contact the radiation safety office and/or radiation oncology physics (see posted call list).

The Cleveland Clinic Foundation

Operating Procedures for Gamma Knife Unit

1. Use of Gamma Knife

Radiation therapists, dosimetrists and/or physicists properly trained in the operation of the Gamma Knife unit are the only individuals authorized to operate the unit. Operation shall be in accordance with the procedures outlined in the User's manual. The unit will not be operated unless a therapist, dosimetrist or physicist is located at the control area. The operator is responsible for ensuring only the patient is in the treatment room prior to beginning treatment and that team members present are wearing their whole body radiation monitor. The operator will also ensure the required safety checks have been performed that day and that all results were acceptable prior to treatment. The therapist/dosimetrist will be responsible for ensuring a written directive is complete prior to commencing treatment of a patient.

2. Safety Device Checks

The radiation therapist, dosimetrist or physicist will perform safety device checks in accordance with the attached checklist, Attachment OP1, prior to operation of the Gamma Knife each day of use. If results exceed expected tolerance, the discrepancy shall be confirmed or negated by additional measurements which shall be documented. The Gamma Stereotactic Radiosurgery (GSR) physicist will be notified of all discrepancies which are confirmed as indicated on the checklist. Documentation of the resolution of all discrepancies will be maintained in the equipment log for the Gamma Knife unit.

3. Periodic Spot-Check Measurements

Once each calendar month an output spot check will be performed with a dosimetry system meeting the requirements in 10 CFR 35.630. These checks will be performed by a physicist trained in operating the Gamma Knife. The results of the output spot check will be reviewed and initialed by a GSR physicist within 15 days. If the GSR physicist performed these measurements, their signature at time of measurement will suffice. Results of this spot check will be documented on the attached monthly spot check form, Attachment OP2.

4. Inspection and Servicing of the Gamma Knife unit

Periodic maintenance and a full inspection/service during source replacement or at five year intervals will be performed only by a person or firm specifically licensed to do so by the NRC or an Agreement State. The Radiation Safety Officer will be responsible for ensuring an individual or firm designated to perform periodic maintenance, inspections or service is so specifically licensed. Procedures for these services will be conducted in accordance with those in the operating/service manual for the Gamma Knife unit.

5. Limitations on Work Done on the Gamma Knife unit

The Radiation Safety Officer (RSO) will review the qualifications of any person or firm prior to the performance of the installation, relocation or removal of the Cobalt-60 sources in the Gamma Knife unit or the entire unit. The RSO will also be notified of any maintenance, adjustment or repair of the unit that involves work on mechanisms that could expose the sources or affect the shielding around the unit. A review of qualifications of the individual or firm will be performed prior to commencing work on the unit. The RSO will document the results of these checks in the equipment log for the Gamma Knife unit.

6. Survey Reports

The RSO will oversee the performance of all surveys required around the Gamma Knife unit at installation, relocation, removal or following source replacement or five year inspection. These surveys will be conducted immediately following completion of such work and prior to any further use of the Gamma Knife unit. The RSO will compile the survey report and file it as required in 10 CFR 35.641. A copy of the survey will be placed in the equipment log and maintained in Radiation Safety as required in 10 CFR 35.641. The RSO must approve the results of the survey prior to further use of the Gamma Knife unit. If any discrepancies are discovered, the RSO will lock the unit and prevent further use of the unit except for additional measurements to permit the resolution of these discrepancies. All actions will be documented in the equipment log.

7. Relocation of the Gamma Knife unit

In the event the location of the Gamma Knife unit is to be changed, the RSO will be notified by the GSR physicist or other team member and shall then be responsible for filing and ensuring receipt of the necessary amendment from the NRC prior to the relocation of the Gamma Knife unit.

8. Recordkeeping

The RSO will maintain copies of the NRC license, applications, amendments and correspondence with the NRC regarding the Gamma Knife license. Radiation Safety maintains personnel dosimetry records, training records, survey meter calibration records, and records of receipt and disposal of radioactive material. Records of safety device checks, dosimetry system calibrations, daily checks, spot check measurements, full calibration measurement, records of full inspection and servicing of the Gamma Knife unit, leak test results and a copy of the surveys conducted for the Gamma Knife unit will be maintained in the vicinity of the control panel of the Gamma Knife unit. All records will be maintained at least for the duration of the NRC license authorizing possession of the Gamma Knife unit.

9. Safety Instructions

Operating procedures for the unit, Attachment OP3, will be posted at the control area of the Gamma Knife unit as will the attached emergency procedures Attachment OP4. Personnel who will operate the Gamma Knife unit, will be trained in the emergency procedures prior to commissioning the unit, upon hiring and at least annual. This training will include practice drills. The RSO will ensure that all training is performed as required.

THE NORTHERN OHIO GAMMA-KNIFE CENTER

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B-type Gamma Knife Quality Assurance Checklist For Each Day of Use

Date: _____ Time: _____ Performed by _____

- | | <u>tolerance</u> | <u>initials</u> |
|--|------------------|-----------------|
| 1 Visual inspection of equipment room, console area, and treatment room | | _____ |
| 2 Apply power to audio and video systems and to survey meter | | |
| - apply check source to treatment room area monitor and verify flashing of lamp-equipped units | | _____ |
| - apply check source to survey meter and verify proper reading (see side panel) | $\pm 20 \%$ | _____ |
| - visually inspect Gamma Unit | | _____ |
| - verify that no one is in the treatment room | | _____ |
| 3 Apply power to Gamma Unit | | |
| - verify operation of indicators (lamps, meters, etc.) | | _____ |
| - verify timer accuracy | $\pm 2 \%$ | _____ |
| 4 Safety systems | | |
| - open cover at rear of _____ mm helmet and verify impossible to treat, close cover | | _____ |
| - initiate "treatment" and verify proper operation of "stop" button | | _____ |
| - initiate "treatment" and verify proper operation of door interlock | | _____ |
| - initiate "treatment" and verify proper operation of Emergency Interrupt | | _____ |
| - verify proper operation of beam status indicators (lamps) | | _____ |
| - verify proper operation of audio and video systems | | _____ |
| - verify that emergency-off buttons prevent initiation of treatment | | _____ |
| 5 Operation | | |
| - verify posting of emergency procedures | | _____ |
| - verify availability of emergency equipment | | _____ |
| - crash cart | | _____ |
| - emergency release rods | | _____ |
| - verify proper operation of system via a mock treatment | | _____ |

Comments: _____

THE NORTHERN OHIO GAMMA-KNIFE CENTER

DRAFT

B-type Gamma Knife Monthly Spot Checks

Date: _____

Performed by _____

		tolerance	S	U	comments
Timer Accuracy					
Timer Reproducibility					
Timer Linearity					
Timer Error					
Timer Termination of Exposure					
Couch Movement Time for Emergency Interrupt					
TV systems					
Audio Systems					
Door Operation					
Door Interlock					
Control Reset Button					
Beam Status Indicators					
Emergency Off Buttons					
Emergency Release Rods					
Trunion Tests	18 mm				
Trunion Tests	14 mm				
Trunion Tests	8 mm				
Trunion Tests	4 mm				
Microswitch Tests	18 mm				
Microswitch Tests	14 mm				
Microswitch Tests	8 mm				
Microswitch Tests	4 mm				
Permanent Radiation Monitor					
Permanent Radiation Monitor Remote Indicator					
Survey Meter					
Operating Instructions					
Emergency Instructions					
NRC postings					
Leak Test					
Output Check	instruments used				
	calibration dates				
	measured value				
	anticipated value				
	% deviation				
	computer value				
	% deviation				

Comments: _____

Reviewed by GSR Physicist: _____

signature

date -----

THE NORTHERN OHIO GAMMA-KNIFE CENTER

DRAFT

B-type Gamma Knife Safety Instructions

Operation:

- 1 Before initiating an exposure, the operator shall conduct a visual inspection of the treatment room to assure that no one other than a patient is left in the room.
- 2 If an emergency interrupt is employed such that the shielding door is open and the patient needs attention; individuals entering the room shall minimize their exposure by staying in the scatter-radiation zone as much as possible, and by minimizing their time within the room.
- 3 If an emergency interrupt was employed, or if a door interlock interruption occurred, the operator shall confirm that no one other than the patient is in the treatment room before continuing treatment.
- 4 If a treatment is stopped (interrupted) by any means, the treatment times (elapsed and remaining) are preserved on the timers. These timers must **not** be reset prior to resumption of treatment.
- 5 Report immediately any abnormal unit operation to radiation oncology physics and also to the radiation safety office (see posted call list).

THE NORTHERN OHIO GAMMA-KNIFE CENTER

DRAFT

B-type Gamma Knife Emergency Procedures

A Power Failure During Treatment

- couch is automatically withdrawn from unit
- physicist assures that the shielding door has closed
 - if it has not, then the team shall remove all individuals from room, close the door and secure the area and call the radiation safety office (see posted call list)
- if power failure was momentary, treatment may be resumed (do not reset timers!)
- if power failure is extended, remove patient from fixation and consult with physicians and/or physicists and/or radiation safety office (see posted call list)

B Power Failure During Treatment & Failure of Couch to Withdraw

- team members as needed to enter treatment room (and to try to stay in scatter area)
- physicist and therapist and/or dosimetrist use emergency release rods to disengage patient
- physician and those finishing with the release rods to assist patient in departing the room
- physicist to close door, secure area
- call radiation safety office (see posted call list)

C Failure of Couch to Withdraw at End of Treatment

- operator to press emergency stop button
- if couch fails to withdraw, team opens door slightly (aserting interlock)
- if couch fails to withdraw, team to enter treatment room and try to stay in scatter area
- physicist and therapist and/or dosimetrist use emergency release rods to disengage patient
- physician and those finishing with the release rods to assist patient in departing the room
- physicist to close door, secure area
- call radiation safety office (see posted call list)

D Radiation Monitor Alarms Other than During Treatment Cycle

- physicist to immediately determine status of shielding door
 - if Gamma Knife shielding door is open, team shall remove all individuals from room, close door and secure area
 - call radiation safety office and then radiation oncology physics (see posted call list)
 - if Gamma Knife shielding door is closed, physicist and/or RSO shall use survey meter to measure the exposure level at the location of the room monitor (normally < 0.1 mR/h) and in front of the shielding door at the rear of the helmet (normally < 1 mR/h). If the measured values exceed expected values, team shall remove all individuals from the room, secure the area, call the radiation safety office and/or radiation oncology physics. Otherwise, if radiation exposure levels are normal, suspect malfunction of the area monitor. Contact the radiation safety office and/or radiation oncology physics (see posted call list).

NOV 27 1996

Xiaowei Zhu
Radiation Safety Officer
Cleveland Clinic Foundation
Radiation Safety Office, W-18
9500 Euclid Avenue
Cleveland, OH 44195-599

Dear Ms. Zhu:

Enclosed is your NRC Material License Number 34-00466-05 which authorizes you to receive, install, and perform operational testing of the Leksell Gamma Knife in accordance with your request.

In order to authorize the use of the device on patients and in research activities outlined in your August 21, 1996 application, it will be necessary for you to submit the following information:

1. Submit copies of the ABR certifications for Drs. Suh and Ciezki. In addition, during my visit to your institution on November 7, 1996, you indicated that Dr. Richard Crownover would possibly be replacing Dr. Ciezki as an authorized user on the license. If this is the case, please submit documentation which clearly demonstrates that Dr. Crownover meets the training and experience criteria outlined in 10 CFR Part 35, Section 35.960;
2. Outline the device specific training that will be provided to Drs. Macklis, Ciezki, and Crownover and also to F. Christopher Deibel, Ph.D., specific to the use of the Gama Knife. This training should be at least 2 weeks in length and include on-the-job training and apprenticeship under a physician (or physicist for F.C. Deibel) authorized user listed on a Gama Knife license. Since the manufacturer will have a trained physician and physicist on site at your institution during the first week of patient treatments, we recommend that Drs. Macklis, Ciezki, Crownover, and F.C. Deibel receive at least one week of their training from these individuals;
3. Submit course completion documentation for the individuals that attended/completed the manufacturer's training course for the Gamma Knife in Sweden and include an outline of the course;
4. Submit a list of the duties and responsibilities of the Radiation Safety Officer relative to this license;

301784

5. Submit your procedures for leak testing the sources and indicate who is responsible for performing the leak tests. Also include your procedures for analyzing the leak tests and the analytical equipment used;
6. Identify any routine preventative maintenance that you will perform on the device and include your procedures and specify the name and qualifications of the individual that will perform the maintenance. Also describe the routine preventative maintenance that's performed by the manufacturer (Leksell) and include the service frequency;
7. Submit the duties and responsibilities of the Radiation Safety Committee (RSC), including their responsibilities relative to the possession and use of the Gamma Knife. Confirm that the membership and meeting frequency of your RSC will satisfy the requirements of 10 CFR Part 35, Section 35.22;
8. Your application dated August 21, 1996 included "draft" operating and emergency (O&E) procedures that need to be expanded upon. Please submit a copy of your step-by-step operating procedures (include the sequence of steps necessary to initiate patient treatment) and emergency procedures for the Gamma Knife. Your emergency procedures should include at least a semi-annual emergency drill to remove a patient from the treatment room and emergency notification names and numbers. Confirm that a copy of the O&E procedures will be posted at the control console and that each authorized user will be provided a copy of the procedure;
9. Submit your quality management program for the Gamma Knife; and
10. Please describe in greater detail the type of research you wish to perform with the Gamma Knife. Your application did not provide any details regarding this use of the device.

Information submitted in response to this letter should be referenced as **additional information to previous Control Number 01784**.

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.

2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user, Radiation Safety Officer, or Teletherapy Physicist 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. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers or Teletherapy Physicists;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. 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.

X. Zhu

-4-

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, 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
Patricia J. Pelke
Nuclear Materials Licensing Branch

License No.: 34-00466-05
Docket No.: 030-34234

Enclosure: As stated

DOCUMENT NAME: M:\03034234.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	<input checked="checked" type="checkbox"/>							
NAME	PPELKE:jaw	<input checked="checked" type="checkbox"/>							
DATE	11/27/96	<input checked="checked" type="checkbox"/>							

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

November 26, 1996

MEMORANDUM FOR: B.J. Holt, Chief, Nuclear Materials Licensing Branch

FROM: Patricia Pelke, License Reviewer *Patricia J. Pelke*

SUBJECT: PRE-LICENSING SITE VISIT FOR CLEVELAND CLINIC
FOUNDATION (CCF), CLEVELAND, OHIO

DATE OF VISIT: November 7, 1996

PURPOSE OF VISIT: To discuss the licensee's application for a new license to possess a Leksell Gamma Stereotactic Radiosurgery (GSR) device (Model No. 23004 Type B) and evaluate the facilities that will accommodate the treatment device and source loading unit.

Program Scope

The licensee submitted an application dated August 21, 1996 for a new GSR device. They indicated in their application that they had a tentative loading date and required the license by November 1, 1996 in order to maintain the shipping schedule. They requested a license for the "new" Elekta Instruments Leksell Gamma System Model 23004 Type B radiation therapy unit. In addition to the new license request, CCF currently has a broad scope license which includes a large and extensive medical use program, an HDR unit used for patient treatment and non-human research studies, two self-contained irradiators, an extensive non-human research and development program, and a survey instrument calibrator. It would be worthy to note that during the period of time that elapsed from the submission of the original application for the GSR device to date of the site visit, the Radiation Safety Officer was replaced.

The GSR device is used in the treatment of selected intracranial anomalies and in Parkinson's disease research. The device contains 201 sealed cobalt-60 sources fixed in position inside a hemispheric shield with 201 collimator ports directed at a single three dimensional focal point inside the unit. The device is comprised of the radiation unit, the operating table and sliding cradle, and the control system.

The projected source loading for the Gamma Knife is November 18 - 22, 1996. The cobalt-60 sources will be loaded by Alpha Omega Services (California License # 2641-70) and Elekta Instruments, Inc. (Georgia License # GA 1153-1). The entire source loading operation will be under the direct control and supervision of these two licensed service contractors. In addition, a representative from the radiation safety staff at CCF (RSO or a GSR physicist) will be physically

present to supervise the source loading operation and to coordinate activities in the event of an emergency.

Source loading of this unit is accomplished by transferring the 201 sources into a portable loading machine which fits securely to the side of the GSR device. The sources are passed through one of five openings into the source body which is indexed to allow the insertion of each source. When all the sources are loaded, the source body is indexed to the central body and the openings sealed with iron plugs.

The GSR device weighs approximately 20 metric tons and is mounted onto a frame to allow movement to a final position where it is leveled and the operating table is mounted. All systems are then checked by the service contractors to insure the device meets the same specifications that it met during QA inspection at the factory.

Site Visit Participants

CCF: Martin Weinhaus, Ph.D., Chief of Medical Physics, GSR Physicist
Xiaowei Zhu, Radiation Safety Officer
Twyla Willoughby, M.S., GSR Physicist

Elekta: Martin Knotts, Director of Technical Services

NRC: Patricia Pelke

Observations

1. The facility that will house the GSR device was still under construction. They were scheduled to pour the floor on 11/9. The treatment room portion of the facility will be completed and the area secured prior to receipt of the sources.
2. A representative from the manufacturer was onsite to evaluate the status of construction and verify loading schedule. It was beneficial for all parties to have an opportunity to meet and discuss the schedule and loading activities. I noted that the RSO was able to clarify what the contractors would be doing onsite and approximate periods of time that particular activities would take.
3. I was able to discuss portions of the application in greater detail with the individuals who had completed the manufacturer's training and identify the deficient areas and what information we would need in order to issue the license. From a timeliness point of view, this onsite negotiation opportunity was extremely beneficial because the licensee was operating on a very tight time schedule. During these discussions, I learned what type of information was covered during the manufacturer's training and I also learned that the manufacturer provides a required service contract to their customers which includes periodic (twice a year) QA/QC checks of the device and associated equipment.

4. Since the facility is still in the construction phase, I indicated that the initial license will be issued to allow CCF to receive, install, calibrate, and perform operational testing of the GSR device, no patient treatment or research activities will be authorized. Once we have reviewed the additional information required (discussed in a 11/5/96 telephone conference and also outlined in the cover letter that will transmit the license), we will amend the license accordingly.

Closing Comment

Based on my observations and discussions with licensee representatives, CCF appears to be well equipped and staffed to house the GSR device. I do not foresee any further licensing delays and upon receipt of the additional information required to use the device on humans and in research activities, I anticipate a timely and expeditious review.

If you have any questions, please contact me at X9868.

cc: C.D. Pederson
R.J. Caniano

DATE: NOVEMBER 13, 1996

NOTE TO : WINNIE ZHU, CLEVELAND CLINIC FOUNDATION
RADIATION SAFETY OFFICER

FROM: PATTY PELKE, NRC REGION III
MATERIALS LICENSING REVIEWER

SUBJECT: NRC LICENSE NO. 34-00466-05
NEW GAMMA KNIFE LICENSE

This is just a note to emphasize that the license authorizes receipt, installation, calibration, and operational testing only of the Gamma Knife. you are not authorized to treat patients or conduct any research activities with the Gamma Knife as of the issue date on the license. Once we have received, reviewed, and accepted your response to the remaining items (6 through 15) of our 11/5/96 telephone conference, we will amend your license accordingly to include treatment of humans/research activities.

Please review the license carefully and if you have any further questions, please give me a call at (630) 829-9868.

A will fax a copy of the license to Elekta (M. Knotts) and Alpha Omega (C. Hedger) per your request.

Thanks ... Patty



THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

Radiation Safety / QQ10
216/444-6645

Ms. Patty Pelke
Material Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

November 7, 1996

Dear Ms. Patty Pelke,

As we discussed on November 5, 1996, the additional information is provided as follows for The Cleveland Clinic Foundation (CCF) Gamma-knife 'license application (reference control number 301784).

We request an expedited phase I approval by the NRC Region III office to issue the license initially authorizing receipt, installation, operational testing and calibration of the device unit. As we discussed, CCF will also submit additional information to support phase II (human use/non human research studies) approval in the near future.

A. RSO responsibility during the source loading

The Radiation Safety Officer or designee* of The Cleveland Clinic Foundation will be physically present on site during the source receipt and loading of Gamma-Knife unit, to supervise source loading activities. The responsibilities of the Radiation Safety Officer or designee will include, but not limited to:

***Designee:**

- **During the initial receipt and loading of the Co-60 sources, Dr. Winehous or Ms. Twyla Willoughby, both are GSR physicists, will be the designee.**

- 1) Ensure only trained individuals are present during the source loading
- 2) Ensure proper personal monitoring devices are provided to the contractors and CCF employees

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- 3) Ensure proper signs and notifications are posted in the treatment room where sources will be loaded
- 4) Ensure radiation dose rate in the surrounding areas are within the acceptable limits during the loading of the source.

B. Correction to 5.1.2 - Sealed source model designation (CCF application dated August 23, 1996)

Page 2 of the Cleveland Clinic's Gamma Knife License Application (dated August 23, 1996) contains a typographic error. Under part 5.1.2, "AM Elekta" should read "AB Elekta". A corrected Page 2 is attached for substitution in the application.

C. Notify NRC of intended source loading schedule

The Cleveland Clinic Foundation will notify the NRC Region III office of intended source loading at least 72 hours prior to the scheduled source receipt and loading of Co-60 sources. CCF will notify NRC Region III regarding any last minute scheduling changes.

D. Securing area and control access during the source receipt and loading

During construction:

A mechanical key-lock will secure the treatment room door. As the building nears completion, that mechanism will be replaced with a key-operated magnetic lock.

During the initial source receipt and loading:

The access to the Gamma-knife building will be controlled by Radiation Safety personnel with the assistance of CCF police if necessary. Only authorized CCF employees and source loading contractors are allowed to be in the building.

Source casket shall always be under the constant surveillance by Radiation Safety personnel or Radiation Oncology personnel during the receipt.

If the source container can not be transferred to the treatment room and locked, the area will be roped off with proper signs ("Caution, Radioactive Material" or "Caution Radiation Area"). CCF security personnel will be posted 24 hours to keep the source container under constant surveillance.

After source casket is transferred to the Gamma-knife building, the treatment room, the door to the room shall be locked when unattended. Keys to the door will be removed and only be possessed by Radiation Safety and Chief physicist of Radiation Oncology or designee, and authorized contractor (Elekta). The contractor will be instructed not to manipulate the Co-60 when radiation Safety staff are not physically present on site.

After sources are loaded, and required surveys are performed:

Security will be accomplished by providing for a locked treatment room (containing Gamma-knife unit) and a locked control console. As stated in CCF's August 23, 1996 application, the Gamma-Knife unit will be secured, key removed, when unattended.

Keys will only be issued to and allowed to be possessed by the individuals approved as GSR Radiation Oncologists, GSR Radiosurgery physicists, GSR Therapists, on the license, and to Radiation Safety Office. A list of individuals to whom the keys are issued will be maintained and a periodic check for possession of keys shall ensure all the keys issued are accounted for.

E. On-site training for source loading contractors

Radiation Safety Officer or designee will provide a brief radiation safety instructions to source loading contractors (Elekta and Alpha Omega workers), including those involved in the handling of the source shipping container and/or source casket. The contractor will also be instructed that, in the event of emergency or if a problem should occur, to contact the Radiation Safety Officer and Chief Physicist of Radiation Oncology immediately.

Radiation Safety Officer:	Ms. Xiaowe (Winnie) Zhu	Pager: 20724
Chief Physicist, Radiation Oncology:	Dr. Martin S. Weinhaus	Pager: 23758

or the CCF police office for immediate attention and assistance.

F. Installation and Loading Schedule

Elekta has informed The Cleveland Clinic Foundation that their preferred installation and loading schedule is:

11/18/96

Delivery and rigging into building of the Gamma Unit, Loading
Machine, and sources (in shipping container which contains the source casket)

The Cleveland Clinic Foundation
Gamma Knife License Application (control 34-00466-01)
Additional Information - November 7, 1996
Page 4 of 4

11/19/96

Positioning and mating of the Loading Machine to Gamma Unit, attachment of the source casket to the Loading Machine

11/20/96

Loading of the sources from the casket into the Gamma Unit

11/21/96

Disassembly of the Loading Machine

11/22/96

Removal of the Loading Machine and shipping container from site

Thank you your timely review of this application. If there are any questions on this information, please contact me at (216)-444-6645. **Additional information regarding Ms. Twyla Willoughby's qualification will be sent out to you under a separate cover.**

Sincerely ,



Xiaowei Zhu, M.S., DABMP
Radiation Safety Officer

CONVERSATION RECORD

TIME 1:15 pm DATE 11/5/96

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

MARTIN WEINHOUS, PH.D. and WINNIE ZHU, M.S.

CLEVELAND CLINIC FOUNDATION

216-444-6298 (MW) / 216-444-6645 (WZ)

FAX NOS. 216-444-6298 (MW) 216-444-4849 (WZ)

SUBJECT

NEW LICENSE APPLICATION FOR CLEVELAND CLINIC GAMMA KNIFE FACILITY
(CN 01784)

SUMMARY

I CONTACTED WINNIE ZHU (RSO) AND MARTIN WEINHOUS (GSR PHYSICIST) TO DISCUSS THE ADDITIONAL INFORMATION NECESSARY TO COMPLETE THE REVIEW. I ALSO INDICATED THAT IN ORDER TO ACCOMMODATE THEIR SOURCE LOAD SCHEDULE, WE WOULD ISSUE THE LICENSE INITIALLY AUTHORIZING RECEIPT, INSTALLATION, OPERATIONAL TESTING AND CALIBRATION OF THE DEVICE ONLY, AFTER WE HAVE RECEIVED A RESPONSE TO ITEMS 1- 5 LISTED BELOW. TREATMENT OF PATIENTS AND HUMAN/NON-HUMAN RESEARCH STUDIES WILL BE AUTHORIZED AT A LATER DATE ONCE THEY HAVE RESPONDED TO THE ADDITIONAL ITEMS (6-15) LISTED BELOW.

1. CLARIFY RESPONSIBILITIES OF THE CLEVELAND CLINIC FOUNDATION (CCF) RADIATION SAFETY STAFF DURING SOURCE RECEIPT/LOADING ACTIVITIES. SPECIFY THE CCF INDIVIDUALS THAT WILL BE PHYSICALLY PRESENT TO SUPERVISE SOURCE LOADING ACTIVITIES;
2. CLARIFY THE MODEL NUMBER OF THE SEALED SOURCES USED IN THE DEVICE. APPLICATION DATED 8/21/96 IDENTIFIED SOURCES WITH "AM" ELEKTA MODEL NO. 43047, THE SEALED SOURCE AND DEVICE REGISTRY INFORMATION WE HAVE INDICATES A MODEL "AB" ELEKTA MODEL NO. 43047;
3. SUBMIT PROCEDURES FOR SECURING AREA AND CONTROLLING ACCESS DURING SOURCE RECEIPT/LOADING. DESCRIBE KEY CONTROL AND ACCOUNTABILITY;
4. CONFIRM THAT YOU WILL NOTIFY NRC REGION III OFFICE AT LEAST 72 HOURS PRIOR TO SCHEDULED RECEIPT AND LOADING OF THE COBALT-60 SOURCES AND THAT YOU WILL NOTIFY US REGARDING ANY LAST MINUTE SCHEDULING CHANGES;
5. DESCRIBE THE ON-SITE TRAINING YOU WILL PROVIDE TO THE SOURCE LOADING CONTRACTOR'S. AS A MINIMUM, CCF SHOULD ESTABLISH AND REVIEW EMERGENCY PROCEDURES IN THE EVENT THAT A PROBLEM OCCURS DURING SOURCE INSTALLATION/ LOADING. YOUR PROCEDURES SHOULD IDENTIFY WHO IS RESPONSIBLE AND INCLUDE EMERGENCY NOTIFICATION NAMES AND PHONE NUMBERS;

THE FOLLOWING INFORMATION WILL BE NECESSARY IN ORDER TO AUTHORIZE USE OF THE DEVICE ON HUMANS AND FOR RESEARCH ACTIVITIES DESCRIBED IN APPLICATION DATED 8/21/96;

6. SUBMIT COPIES OF THE ABR CERTIFICATIONS FOR DRS. SUH AND CIEZKI;
7. OUTLINE THE DEVICE SPECIFIC TRAINING THAT WILL BE PROVIDED TO DRS. MACKLIS AND CIEZKI AND ALSO TO F. CHRISTOPHER DEIBEL, PH.D., SPECIFIC TO THE USE OF THE GAMMA KNIFE. THIS TRAINING SHOULD BE AT LEAST 2 WEEKS (80 HOURS) IN LENGTH AND INCLUDE ON THE JOB TRAINING AND APPRENTICESHIP UNDER A PHYSICIAN (OR PHYSICIST FOR F.C.DEIBEL)

AUTHORIZED USER LISTED ON A GAMMA KNIFE LICENSE. SINCE THE MANUFACTURER WILL HAVE A TRAINED PHYSICIAN AND PHYSICIST ON SITE AT YOUR INSTITUTION DURING THE FIRST WEEK OF PATIENT TREATMENTS, WE RECOMMEND THAT BOTH DRs. MACKLIS AND CIEZKI AND F.C. DEIBEL RECEIVE AT LEAST ONE WEEK OF THEIR TRAINING FROM THESE INDIVIDUALS;

8. IN ORDER TO LIST TWYLA WILLOUGHBY ON THE LICENSE AS A GSR PHYSICIST AND A NON-HUMAN USE AUTHORIZED USER, IT WILL BE NECESSARY TO SUBMIT ADDITIONAL DOCUMENTATION WHICH CLEARLY INDICATES THAT SHE SATISFIES THE REQUIREMENTS OF 10 CFR PART 35, SECTION 35.961(c) AND DEMONSTRATE THAT HER EXPERIENCE HAS INCLUDED ITEMS IN 10 CFR 35.59, 35.632, 35.634, AND 35.641;
9. SUBMIT COURSE COMPLETION DOCUMENTATION FOR THE INDIVIDUALS THAT ATTENDED/COMPLETED THE MANUFACTURER'S TRAINING COURSE FOR THE GAMMA KNIFE IN SWEDEN AND INCLUDE AN OUTLINE OF THE COURSE;
10. SUBMIT A LIST OF THE DUTIES AND RESPONSIBILITIES OF THE RSO AT THIS FACILITY;
11. SUBMIT PROCEDURES FOR LEAK TESTING THE SOURCES AND INDICATE WHO IS RESPONSIBLE FOR PERFORMING LEAK TESTS;
12. IDENTIFY ANY ROUTINE PREVENTATIVE MAINTENANCE THAT YOU WILL PERFORM ON THE DEVICE, INCLUDE YOUR PROCEDURES AND SPECIFY THE NAME AND QUALIFICATIONS OF THE INDIVIDUAL(S) THAT WILL PERFORM THE MAINTENANCE;
13. SUBMIT THE DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY COMMITTEE, INCLUDING THEIR RESPONSIBILITIES RELATIVE TO THE POSSESSION AND USE OF THE GAMMA KNIFE. INCLUDE MEETING FREQUENCY AND NAMES OF MEMBERS. NOTE THAT YOUR RSC MUST SATISFY THE REQUIREMENTS OF 35.22.
14. YOUR 8/21/96 APPLICATION INCLUDED "DRAFT" OPERATING AND EMERGENCY PROCEDURES THAT NEED TO BE EXPANDED UPON. PLEASE SUBMIT A COPY OF YOUR STEP-BY-STEP OPERATING PROCEDURES (INCLUDE SEQUENCE OF STEPS NECESSARY TO INITIATE TREATMENT) AND EMERGENCY PROCEDURES FOR THE GAMMA KNIFE, INCLUDE AT LEAST A SEMI-ANNUAL EMERGENCY DRILL TO REMOVE A PATIENT FROM THE TREATMENT ROOM AND EMERGENCY NOTIFICATION NAMES AND NUMBERS. CONFIRM THAT A COPY OF EACH WILL BE POSTED AT THE CONTROL CONSOLE AND THAT EACH AUTHORIZED USER WILL ALSO HAVE A COPY OF THE O&E PROCEDURES; AND
15. SUBMIT YOUR QUALITY MANAGEMENT PROGRAM FOR THE GAMMA KNIFE.

ACTION REQUIRED

FAX COPY TO LICENSEE; RESPOND WITHIN 15 DAYS TO ITEMS 1-5 AND WITHIN 30 DAYS FOR REMAINING (ITEMS 6-15). REFER TO CN 01784

NAME OF PERSON DOCUMENTING CONVERSATION
PATRICIA J. PELKE

SIGNATURE

11/6/96

DATE



ACTION TAKEN

SIGNATURE

TITLE

DATE



THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

Radiation Safety / QQ10
216/444-6645

Ms. Cassandra Frazier
Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

October 9, 1996

Dear Ms. Frazier:

Attached you will find **additional information** for **reference control # 301784** for the application for a Gamma Knife system for The Cleveland Clinic Foundation (CCF), NRC License # 34-00466-01. This information changes the submitted RSO as I am leaving CCF on October 11, 1996; the addition of Ms. Twyla Willoughby as a GSR physicist and nonhuman user; changes to therapists' names submitted; a modification to the description of the training provided by Leksell; incorporates some changes to the door for the treatment room and provides updated drawings as some discrepancies were noted in the original drawings from Attachment 6. I have submitted new pages for the original application from August 22, 1996, please replace pages 3, 4 and 5 from that application, the three new drawings for Attachment 6 and the information in Attachment 3. Please add the additional information to Attachments 2 and 4. Changed information is bolded and underlined.

Also the original team has completed the two week training in Sweden, this team consisted of Drs. Barnett, Miller, Suh, Weinhaus and Ms. Willoughby.

If there are any questions on this information, please contact me prior to October 11, 1996 or after that Ms. Zhu at (216) 444-6645. Thank you for your timely review of this information.

Sincerely,

Judy A. McKenna, M.S., DABR
Director, Radiation Safety

ATT.

RECEIVED
OCT 10 1996
REGION III

Item 7 (cont.)

Proposed Authorized Users -- Nonhuman Use

Attachment 2 contains the required Supplement A forms for the following individuals:

Roger M. Macklis, M.D.
John H. Suh, M.D.
Jay P. Ciezki, M.D.
Martin S. Weinhaus, Ph.D.
F. Christopher Deibel, Jr., Ph.D.
Twyla R. Willoughby, M.S.

Proposed Radiation Safety Officer

Attachment 3 contains the required Supplement A for Ms. Xiaowei Zhu, M.S., the proposed RSO for NRC License 34-00466-01 as per license application 9/27/96.

Proposed Gamma Stereotactic Radiosurgery (GSR) Physicist

Attachment 4 contains the required Supplement A for the proposed GSR physicists:

Martin S. Weinhaus, Ph.D.
F. Christopher Deibel, Jr., Ph.D.
Twyla R. Willoughby, M.S.

Item 8 - Training for Individuals working in or frequenting Restricted Areas

8.1. Training program

8.1.1 Training Program for Individuals responsible for GSR Treatment of Patients
The "team" for the GSR program will include the GSR physicist, neurosurgeon, radiation oncologist, radiation therapist and/or dosimetrist, nurse as needed and anesthesiology support as needed. A qualified neurosurgeon or radiation oncologist will see the patient as the intake physician and determine if the case seems reasonable for radiosurgery. If so, the case will be presented at a radiosurgery conference and both a qualified neurosurgeon and a qualified radiation oncologist must agree that the case is appropriate before the patient is scheduled. Both the neurosurgeon and the radiation oncologist will discuss risks and obtain informed consent for the overall procedure with each emphasizing the issues most germane to their specialty. The neurosurgeon is responsible for the application and removal of the stereotactic head frame, determines the lesion boundaries and confirms the appropriateness of the overall treatment plan. The radiation oncologist prescribes the appropriate radiation doses on the written directive and the qualified radiosurgery physicist is responsible for overseeing the delivery of the prescription and quality assurance aspects of treatments. Each plan will be signed by both physicians and the physicist prior to implementation. At least one of the qualified physicians will be physically present at all times during the actual procedure. For unstable cases (as judged by the team), both the neurosurgeon and radiation oncologist will be

Item 8.1.1 (cont.)

present. The therapist monitors the patient and equipment controls during treatment and assists with patient positioning.

Neurosurgeons: Gene H. Barnett, M.D.
 David W. Miller, M.D.

Radiation Oncologists: Roger M. Macklis, M.D.
 John H. Suh, M.D.
 Jay P. Ciezki, M.D.

Radiosurgery Physicists: Martin S. Weinhaus, Ph.D.
 F. Christopher Deibel, Jr., Ph.D.
 Twyla R. Willoughby, M.S.

Therapists: Mary DeVito, RTT
 Pam Saffle, RTT
 Kelly Kardos, RTT
 Patricia Barrett, RTT, CMD
 Diana Mattson, RTT

Dosimetrists: Dave Abraham, RTT, CMD
 Carole Belfi, RTT, CMD
 Mark Murray, RTT, CMD
 Lynn Vukich, RTT, CMD

Nurse: Joan Wendel, RN, MSN, OCN
 Arlene White, RN
 Jeannie Hamker, RN
 Laura Laufman, RN

The initial team of neurosurgeon(s), radiation oncologist(s) and physicist(s) will receive instruction in the technical operation and maintenance of the unit by attending classes offered by the manufacturer. Subsequently, other neurosurgeons, radiation oncologists, physicists, therapists, dosimetrists and nurses will receive apprenticeship and on-the-job training. Training will also be provided specific to procedures incorporated into the license application for CCF. This training will also be received by a replacement to any of these identified individuals. At least annually a refresher training will be provided which addresses any significant changes in duties, regulations, terms of the license, equipment, or procedures. Radiation Safety shall ensure all individuals are properly trained and will maintain documentation of the training at least until termination of this license.

Item 8.1.1. (cont.)

For nonhuman use any one of the individuals listed in Item 7 either a physicians or physicists will be present during the operation of the unit.

8.1.2., 8.1.3, 8.1.4, and 8.1.5 - see Attachment 5.

8.3 - see Attachment 5. (no 8.2 identified in draft guide)

Item 9 - Facilities and Equipment

9.1 Facility diagram

See Attachment 6 for annotated plans and elevation drawings. All concrete indicated is standard density 147 pounds/cubic foot. The proposed location is a new one story building with no basement. The door to the treatment room is a manually operated door which is interlocked with the Gamma Knife system and a key switch controlled by an electromagnetic lock. These systems will be activated to prevent entry after hours and are on emergency back-up power in the event of a power failure.

9.2 Survey Instruments and Radiation Monitors

- A dedicated portable survey meter meeting the requirements of 10 CFR 35.620 will be available in the GSR area. Survey meters will be calibrated at least annually by Radiation Safety using the Victoreen Tech Ops, Cesium-137 calibrator (NRC License 34-00466-01), records of which will be maintained by Radiation Safety for at least 3 years.
- A permanently installed radiation monitor, with an independent source of backup power, will be in use at all times the system is operated. The monitor will produce a flashing light during source out conditions and will be visible upon entry into the treatment room. Verification of performance of this system will be conducted each day the system is to be operated. Results of these checks will be documented and retained for a period of at least 3 years.
- A dosimetry system meeting the requirements in 10 CFR 35. 630 will be used for full calibrations and spot checks. Records of the calibrations of the dosimetry system will be maintained at least through the use of the equipment.
- Equipment available in Radiation Safety for evaluation of leak test samples includes a Tennelec LB 5100 Low background proportional counter equipped with a gamma option (NaI detector); a sodium iodide detector and multichannel analyzer system; or a Beckman 4000 Gamma Counter. All systems provide the ability to detect less than or equal to 0.005 μCi .

(no 9.2, 9.3 or 9.4 identified in draft guide)

The Cleveland Clinic Foundation
Gamma Knife License ApplicationAugust 22, 1996 - REVISED - October 9, 1996
Attachment 2 - additionSUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If physician)		
Twyla R. Willoughby M.S.				
3. CERTIFICATION				
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)				
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	LECTURE/LABORATORY COURSE (HOURS)	FORMAL SUPERVISED OUT/LABORATORY EXPERIENCE (MONTHS)	
RADIATION PHYSICS AND INSTRUMENTATION	See Attached. A			
RADIATION PROTECTION				
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES				
RADIATION BIOLOGY				
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	See Attached. B			
* Experience with radioisotopes includes work with and supervision of qualified technicians handling materials.				
1. Review of safety related procedures and compliance with applicable regulations of				
2. Initial training of personnel in handling and use of radioactive materials and				
3. Supervision of all personnel and safety matters				
4. Acquisition of equipment and (if needed) training for use of equipment				
5. Knowledge of applicable radiation safety, quality control, and emergency procedures for handling and using radioisotopes				
I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of person submitting)				
Certification of MDACC training through UTHSC/CSBS Kenneth R. Hogstrom				DATE
TYPED OR PRINTED NAME				8/8/96
Kenneth R. Hogstrom, PhD				
NAME OF INSTITUTION				
M.D. Anderson Cancer Center - Box 94				
MAILING ADDRESS				
1515 Holcombe Blvd.				
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER	
Houston	TX	77030	L00466	
WARNING: 18 U.S.C. Section 1001, Act of June 25, 1946, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States or to any matter within its jurisdiction.				

4.) Certification: List of Training
Twyla Willoughby, M.S.

Field	Locations	Courses (Hours)	Formal Supervised Training, OJT, Labs
Radiation Physics Instrumentation	<i>M.D. Anderson C.C. (1991-1995)</i>	Med. Phys I (36) Med. Phys II (36) Adv. Rad. Phys. (36) Rad Detection (36) Short Course II, III (100)	Med. Phys Rotation (200) Short Course Labs (30)
	<i>Cleveland Clinic Found. (1995-1996)</i>		Nucletron Training (2)
Radiation Protection	<i>M.D. Anderson C.C. (1992)</i>	Radiation Protection (36) Nuclear Medicine (36) Short Courses I, II, III (10)	
	<i>Cleveland Clinic Found. (1995-1996)</i>		OJT (20)
Mathematics for use, Meas., Shielding of Radioactive Sources	<i>M.D. Anderson C.C. (1991-1995)</i>	Math for Med. Phys. (36) Short Course I (80) Nuclear Medicine (5) Radiation Protection (20)	Brachy. Rotation (20)
	<i>Cleveland Clinic (1995-1996)</i>		OJT (20)
	<i>Leksell Gamma Knife Training</i>		Meas. Procedure (10)
Radiation Biology	<i>M.D. Anderson C.C. 1992</i>	Radiation Biology (3) Short Course II (5)	

5.) Experience with Radioactive Materials.

Isotope	Maximum Amount Single Application	Where	Duration	Type of Use
⁶⁰ Co	~ 6000 Ci	M.D. Anderson	1 year	Calibration, Rad. Survey, Teletherapy Treatments.
		Cleveland Clinic Found.	3 mos.	Teletherapy Treat.
¹³⁷ Cs	50 mg Ra	M.D. Anderson	1 year	Laboratory Gyn Treatments
		Cleveland Clinic Found.	3 mos.	Gyn Treatments
¹²⁵ I	50 mCi	Cleveland Clinic Found.	1 yr. - ongoing	Permanent Implants
¹⁹² Ir	10 Ci	Cleveland Clinic Found.	1 yr - ongoing	HDR treatments of Gyn, Head and Neck, Sarcomas, Prostate, Rectum

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION	
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER			
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Xiaowei Zhu		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED N/A	
3. CERTIFICATION			
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C	
American Board of Medical Physics	Medical Health Physics	April, 1996	
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	See Attachment 1	386	3600
b. RADIATION PROTECTION	See Attachment 1	160	3600
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	See Attachment 1	430	2800
d. RADIATION BIOLOGY	See Attachment 1	40	1500
e. RADIOPHARMACEUTICAL CHEMISTRY	See Attachment 1	56	2800
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)			
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS
		See Attachment 2	

Attachment 1 - "Training received in basic radioisotope handling techniques"

Field of training	Clock hours in lecture or lab	Clock hours of supervised on-the-job experience
	Locations (hours)	Location (hours)
4. a.	A(250), B(120), C(16)	C(2160), D(1440)
4. b.	B(144), C(16)	C(2160), D(1440)
4. c.	A(378), B(40), C(16)	C(1680), D(1120)
4. d.	B(32), C(8)	C(900), D(600)
4. e.	B(48), C(8)	C(1680), D(1120)

Notation for Locations and date:

Location	Date
A. Beijing Normal Univ. Beijing, China	1981-1987, under graduate student and graduate student majored in Physics (B.S.), graduate study in Solid State Physics
B. Texas A&M Univ. College Station, TX	1987-1989, graduate student, Research Assistant majored in Health Physics (M.S.)
C. University of Pennsylvania	1989-1993, full time Medical Health Physicist, part time Ph.D candidate, majored in Biomedical Engineering
D. Cleveland Clinic Foundation	1993-Present, Full time Medical Health Physicist

Attachment 2 - " Experience with Radiation (actual use of radioisotope or equivalent experience)

Isotope	Activity used at one time	Location	Clock hours	Type of use
Cs-137 (sealed) for irradiators	≤ 4000 Ci	CCF	3 years	radiation protection support
Radionuclides for nuclear medicine i)	≤ 250 mCi	CCF ^a , UPENN ^b	7 years	radiation protection support
Radioactive sources for brachytherapy ii)	≤ 10 Ci	CCF ^a , UPENN ^b	7 years	radiation protection support
Radionuclides for biomedical research iii)	≤ 10 mCi	CCF ^a , UPENN ^b	7 years	radiation protection support

a. CCF- The Cleveland Clinic Foundation, Cleveland, OH

b. UPENN - University of Pennsylvania, Philadelphia, PA

i) For Nuclear Medicine:

Tc-99m, I-131, I-125, Sr-89, P-32, Co-57 sealed, Ga-68 sealed, Tl-201, F-18, O-15, etc..

ii) For Brachytherapy:

Cs-137, Ir-192 include source for HDR, I-125, Pd-103.

iii) For Biomedical Research:

C-14, H-3, S-35, P-32, I-125, Cr-51, etc..



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TEST CONSULTANT

James Hecht, Ph.D.

May 16, 1996

Xiaowei Zhu
9836 Silverleaf Dr
North Royalton, OH 44133

Dear Xiaowei:

I am pleased to inform you that the ABMP has accepted the recommendation of its Examination Panel that you be awarded Certification in Medical Physics with Special Competence in Medical Health Physics.

With best personal congratulations,

Sincerely yours,

Faiz M. Khan, Ph.D.
Chairman, American Board of Medical Physics

*As of September 27, 1996, the Certification has not been received.
Will forward a copy of the Certification upon receiving.

Xiaowei (Winnie) Zhu

9836 Silverleaf Drive
North Royalton, Ohio 44133

Voice/Fax: (216) 237-8831
E-mail: zhux@cesmtp.ccf.org

Objective: A Radiation Safety Officer position offering challenges and responsibilities where technical expertise and management skills in Health Physics and Diagnostic Physics would be of value.

Certification: ABMP (American Board of Medical Physics) board certification in Medical Health Physics, 1996.

Employment:

- 1993 - present **Medical Health Physicist**, Radiation Safety Office, The Cleveland Clinic Foundation, Cleveland, OH.
- 1989 - 1993 **Medical Health Physicist**, Radiation Safety Office, Univ. of Pennsylvania, Philadelphia, PA.
- 1987 - 1989 **Research Assistant**, Texas Engineering Experiment Station, Texas A&M Univ. College Station, TX.

Education:

- 1987 - 1989 **M.S. in Health Physics** (1989), Department of Nuclear Engineering, Texas A&M Univ., College Station, TX.
- 1985 - 1987 **Graduate Study in Solid State Physics**, Institute for Low Energy Nuclear Physics, Beijing Normal Univ., Beijing, China.
- 1981 - 1985 **B.S. in Physics** (1985), Dept. of Physics, Beijing Normal Univ., Beijing, China.

Professional Experience:

Have worked under academic/medical broad scope licenses with wide range of duties and progressive responsibilities for over seven years. Current professional health physics experience, supervisory skills, and working knowledge of NRC, health physics related DOT, FDA, EPA, and JCAHO regulations, Pennsylvania, Ohio State Radiation Protection Rules, and ICRP, NCRP recommendations.

Supervision and Management: Supervising technical staff in various radiation safety programs from routine duties to emergency and accident response. Hands-on experiences in performing and management of radioactive waste program, clinical department and biomedical research lab audits and inspections, internal and external personnel monitoring programs, Instrument calibration and medical equipment QA programs, etc.

License Review and Committee Involvement: Extensive experience in radioactive material use license review, include biomedical research, animal research, and human subject clinical research protocol reviews. Comprehensive knowledge in NRC and FDA compliance issues associated with the license application and approval. Extensive working experiences in advise researchers and practitioners in protocol design for various committee approval and regulatory compliance. Member of Radiology QA Committee.

Compliance Audit and Health Physics Supports: Audit clinical departments (Nuclear Medicine, Radiation Oncology, Radiology) and biomedical research labs for federal and state regulatory compliance. Providing health physics technical supports and safety recommendations.

Training and Teaching: Design and implement training programs for radiation and radioactive material users, include researchers, physicists, nurses, technologists, etc. Many years experiences in teaching residency program and schools for technologists.

Procedure Development: Develop and review implement of procedures in various radiation safety programs. Have written numerous standard operating procedures for inter-department and intra-department uses. Good people skills and experience in effective communication.

Technical Skills and Knowledge

Instrument Use and Calibration: Working knowledge in operating and calibrating radiological survey and counting instruments, spectrometers, nuclear medicine dose calibrators. Practical training in quality control program for nuclear medicine imaging systems.

Test of Energized Diagnostic & Research X-ray equipment: Working experience and test report review in diagnostic x-ray equipment (radiographic, fluoroscopic, CT, and dental unit, diffraction, cabinet units, and electromicroscope).

Internal and External Dosimetry Calculation: Thorough knowledge in MIRD dose calculation. Internal and external radiation dose assessments for both routine monitoring and accidental dose evaluations. Interested in microdosimetry research and application.

Shielding Design and Evaluation: Experience and in-depth knowledge in shield design and evaluation for both diagnostic and radiation therapy facilities. Provide advises to biomedical researchers in using proper shielding for work bench and waste storage.

Computer: A fluent user of PC, Macintosh, and VAX system. Familiar with major spreadsheets, graphic, word processing software. Frequent use of numerical analysis and FORTRAN and BASIC programming.

Continuous Professional Development:

- Magnetic Resonant Imaging: AAPM summer school on MRI, Banf, Canada, July, 1992.
- Waste Management: Mix waste workshop, Minneapolis, Minnesota, November, 1993.
- Ohio Radioactive Materials (RAM) User Group - RAM Waste Workshop, November, 1994
- American Association of Physicist in Medicine Annual meeting July, 1994
- Fluoroscopy: Exposure, Injuries, and Intervention Procedures, Univ. of Virginia, Sep., 1995.
- Big 10 RSO meeting, Univesity of Chicago, Chicago, IL, Sep., 1996

Publication: D. Mozley and X. Zhu *et al.* The dosimetry of iodine-123-labeled TISCH: A SPECT imaging agent for D1 dopamine receptor. *J. Nucl Med.* Vol.34(2):208-13. Feb. 1993.

Personal: Enjoy travel, out door activities, reading, classical and easy music. Member of American Health Physics Society, American Association of Physicist in Medicine, Cleveland Association of Medical Physicist.

References: Available upon request

The Cleveland Clinic Foundation
Gamma Knife License Application
August 22, 1996 REVISED - October 9, 1996
Attachment 4 - addition

SUPPLEMENT A
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

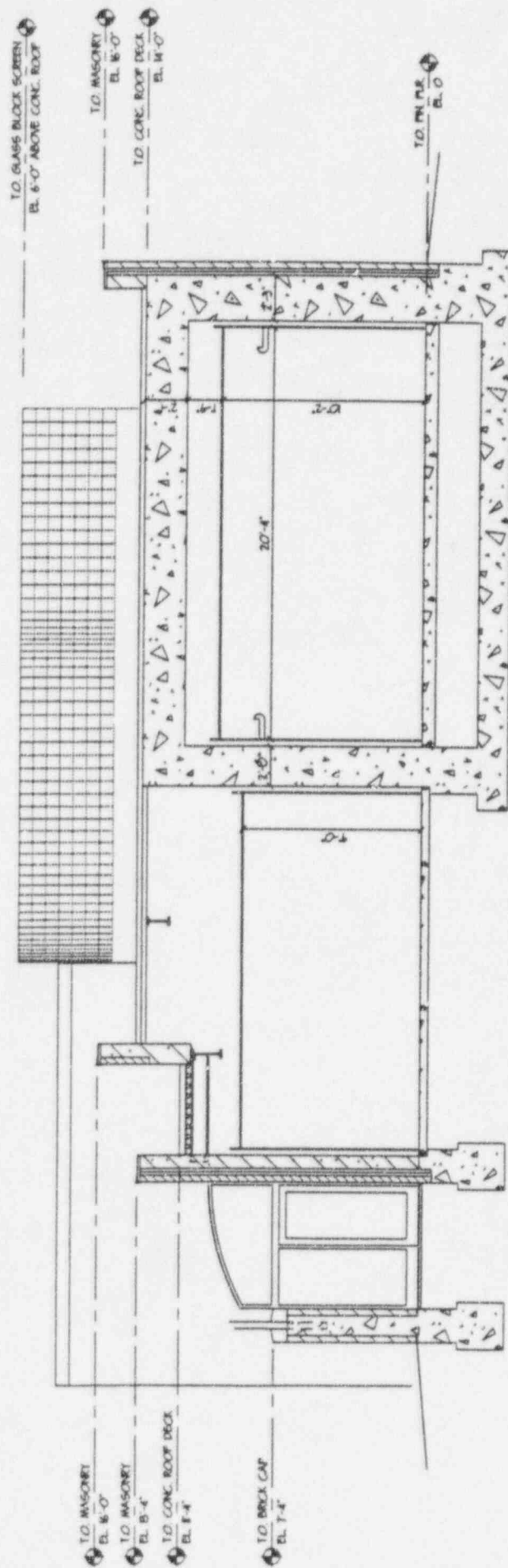
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <i>Twyla R. Willoughby M.S.</i>		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (If applicable)		
3. CERTIFICATION				
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES (To be completed by institution providing training)				
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING		
		LECTURE/LABORATORY COURSE (MIN)	FORMAL SUPERVISED OUTLABORATORY EXPERIENCE (MONTH)	
RADIATION PHYSICS AND INSTRUMENTATION	See Attached. A			
RADIATION PROTECTION				
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES				
RADIATION BIOLOGY				
5. EXPERIENCE WITH RADIOACTIVE MATERIALS* (Actual use of radioisotopes or radioactive substances)				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	See Attached. B			
* Experience with sealed radioactive sources under the supervision of qualified personnel should be included.				
1. Removal of sealed sources from containers and transfer into containers for use in therapy or research.				
2. Initial loading of sealed sources into containers for use in therapy or research.				
3. Calibration of dose calibrators and survey meters.				
4. Preparation of calibration charts and transfer of data to file in a log or notebook.				
5. Supervision of sealed source radiation safety, quality control, and emergency procedures for handling and using sealed sources.				
6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF (Signature of person submitting)				
Certification of MDACC training through UTHSC/GBBS <i>Kenneth R. Hogstrom</i>				DATE <i>8/8/96</i>
TYPED OR PRINTED NAME <i>Kenneth R. Hogstrom, PhD</i>				
NAME OF INSTITUTION <i>M.D. Anderson Cancer Center - Box 94</i>				
MAILING ADDRESS <i>1515 Holcombe Blvd.</i>				
CITY <i>Houston</i>	STATE <i>TX</i>	ZIP CODE <i>77030</i>	RADIOACTIVE MATERIALS LICENSE NUMBER <i>L00466</i>	
WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 949, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States or in any matter within its jurisdiction.				

4.) Certification: List of Training
Twyla Willoughby, M.S.

Field	Locations	Courses (Hours)	Formal Supervised Training, OJT, Labs
Radiation Physics Instrumentation	<i>M.D. Anderson C.C. (1991-1995)</i>	Med. Phys I (36) Med. Phys II (36) Adv. Rad. Phys. (36) Rad Detection (36) Short Course II, III (100)	Med. Phys Rotation (200) Short Course Labs (30)
	<i>Cleveland Clinic Found. (1995-1996)</i>		Nucletron Training (2)
Radiation Protection	<i>M.D. Anderson C.C. (1992)</i>	Radiation Protection (36) Nuclear Medicine (36) Short Courses I, II, III (10)	
	<i>Cleveland Clinic Found. (1995-1996)</i>		OJT (20)
Mathematics for use, Meas., Shielding of Radioactive Sources	<i>M.D. Anderson C.C. (1991-1995)</i>	Math for Med. Phys. (36) Short Course I (80) Nuclear Medicine (5) Radiation Protection (20)	Brachy. Rotation (20)
	<i>Cleveland Clinic (1995-1996)</i>		OJT (20)
	<i>Leksell Gamma Knife Training</i>		Meas. Procedure (10)
Radiation Biology	<i>M.D. Anderson C.C. 1992</i>	Radiation Biology (3) Short Course II (5)	

5.) Experience with Radioactive Materials.

Isotope	Maximum Amount Single Application	Where	Duration	Type of Use
⁶⁰ Co	~ 6000 Ci	M.D. Anderson	1 year	Calibration, Rad. Survey, Teletherapy Treatments.
		Cleveland Clinic Found.	3 mos.	Teletherapy Treat.
¹³⁷ Cs	50 mg Ra	M.D. Anderson	1 year	Laboratory Gyn Treatments
		Cleveland Clinic Found.	3 mos.	Gyn Treatments
¹²⁵ I	50 mCi	Cleveland Clinic Found.	1 yr. - ongoing	Permanent Implants
¹⁹² Ir	10 Ci	Cleveland Clinic Found.	1 yr - ongoing	HDR treatments of Gyn, Head and Neck, Sarcomas, Prostate, Rectum

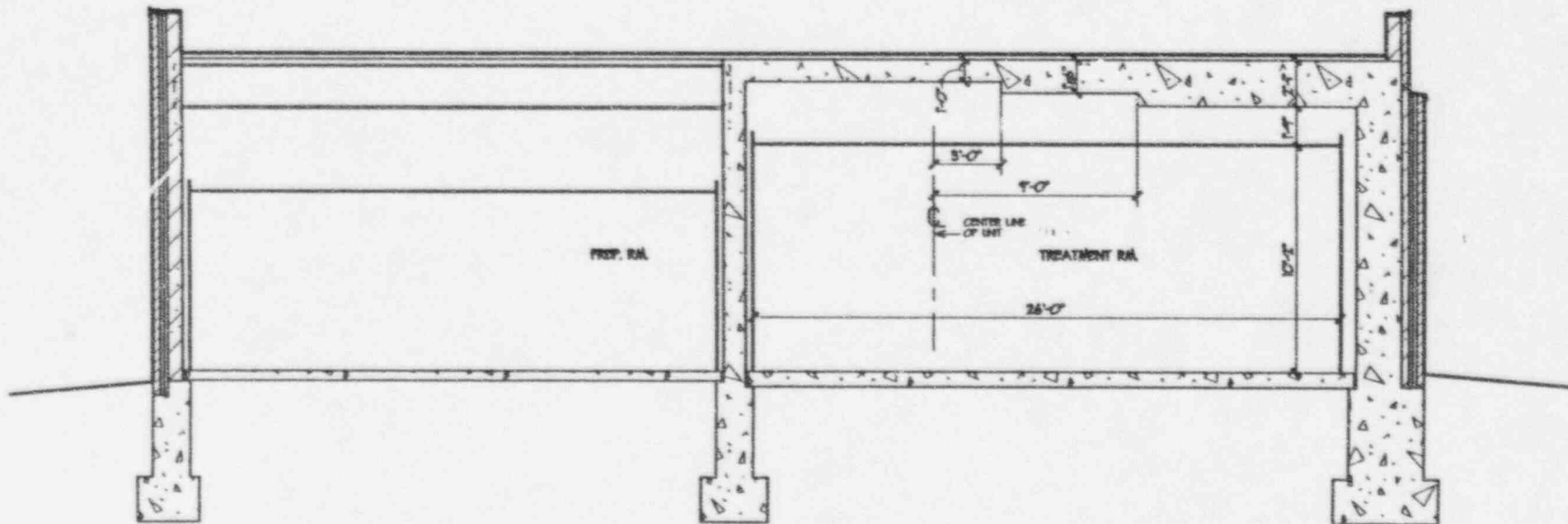


EAST SECTION

SCALE: 1/8"=1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS



SOUTH SECTION

SCALE: 1/8"=1'-0"

THE CLEVELAND CLINIC FOUNDATION
GAMMA KNIFE CENTER

COLLINS, RIMER AND GORDON
ARCHITECTS