Edward Hines, Jr. Hospital Hines IL 60141

Veterans Administration

July 29, 1987

In Reply Refer To:

Director
Radioisotope Licensing Branch
Division of Fuel and Cycle Material Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

SUBJ: Proposed Amendment to the USNRC License 12-01087-07, held by Hines VA Hospital, Hines, Illinois 60141

Dear Sir:

Enclosed are the original and three copies of the proposed amendment to our USNRC license. Please advise us if additional materials are required to support this amendment request.

If I can be of further assistance, please contact my Staff Assistant, Nick G. Guzzi, on FTS 387-2500.

Sincerely,

William Best

"FOR AND IN THE ABSENCE OF"
JOHN R. FEARS
Director

8/11/87

W. FLETCHER, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, DC 20420

NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

Approved by OMB 3150-0041

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

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

Veteran's Administration
Edward Hines Jr. Medical Center
Hines, Illinois 60141

TELEPHONE NO.: AREA CODE (312) 343- 7200

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

(See Item 1a.)

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Lawrence Case (HRSO)

TELEPHONE NO.: AREA CODE (312) 343-7200 X2678

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 12-01087-07
c. ☐ RENEWAL OF LICENSE NO. _____

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

See Item 12 A of current
License 12-01087-07, Amendment No. 41

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

Lawrence Case,
Hospital Radiation Safety Officer

6. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		22850 (See attachmt)

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

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Uranium (depleted); U-238	40 lbs., solid	Sufficiently small to satisfy the definition of "depleted uranium";6mCi	Storage Safe (Container) for Device A.

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE (See attachment)

- ☐ Names and Specialties Attached; and
- ☐ Duties as in Appendix B; or _____ *(Check One)*
- ☐ Equivalent Duties Attached

8. TRAINING AND EXPERIENCE (Not applicable)

- ☐ Supplements A & B Attached for Each Individual User; and
- ☐ Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)* (See attachment)

- ☐ Appendix C Form Attached; or
- ☐ List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS (See attachment)

- ☐ Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached; and
- ☐ Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT (See Item 20 A)

- ☐ Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM (See Item 20)

- ☐ Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL (See item 20)

- ☐ Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)* (Not applicable)

- ☐ Appendix F Procedures Followed; or
- ☐ Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)* (See Item 20)

- ☐ Appendix G Rules Followed; or
- ☐ Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)* (See Item 20)

- ☐ Appendix H Procedures Followed; or
- ☐ Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)* (See Item 20)

- ☐ Appendix I Procedures Followed; or
- ☐ Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- ☐ Appendix J Form Attached; or (See attachment)
- ☐ Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)* (Not applicable)

- ☐ Appendix K Procedures Followed; or
- ☐ Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES (See attachments)

- ☐ Detailed Information Attached; and
- ☐ Appendix L Procedures Followed; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133) (Not applicable)

- ☐ Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS Not applicable

- ☐ Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- ☐ Detailed Information Attached (Not applicable)

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 6a — Radioactive Material for Medical use

An increase in our possesion limit from 2100 mCi to 22850 mCi is necessitated by the purchase of two new Medical Units that contain sealed sources, hereafter referred to as Device A and Device B.

Device A

Device Type:	Remote Afterloading Brachytherapy Irradiator.
Manufacturer:	Isotopen - Technik Dr. Sauerwein/ GmbH Bergische St. 16, D-5657 Haan, West Germany.
Model Name/Number:	Gamma Med II-i.
Distributor:	Mick Radio-Nuclear Instruments, Inc. 1470 Outlook Avenue Bronx, New York 10465
Radionuclide:	Iridium-192.
Sealed Source Manufacturer and Model Number:	Byk-Mallinckrodt CIL B.V. 1775 ZG, Petten, Holland Dwg. No. GM 252-20-001 Type A Shipping Container/Source Charger Dwg. No. Tr 131-05-000.
Maximum Activity:	No single source to exceed a nominal 10 curies; two sources of not more than a nominal 20 curies.
Number of Sources:	Two.

****

* NOTE: This device is listed in the NRC's "Registry of Radioactive Sealed Sources and Devices" as: No. NY 453 D 201 S, dated September 10, 1986. *

****

Intended Use: Medical Irradiator for interstitial and intracavitary treatment of human cancers.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

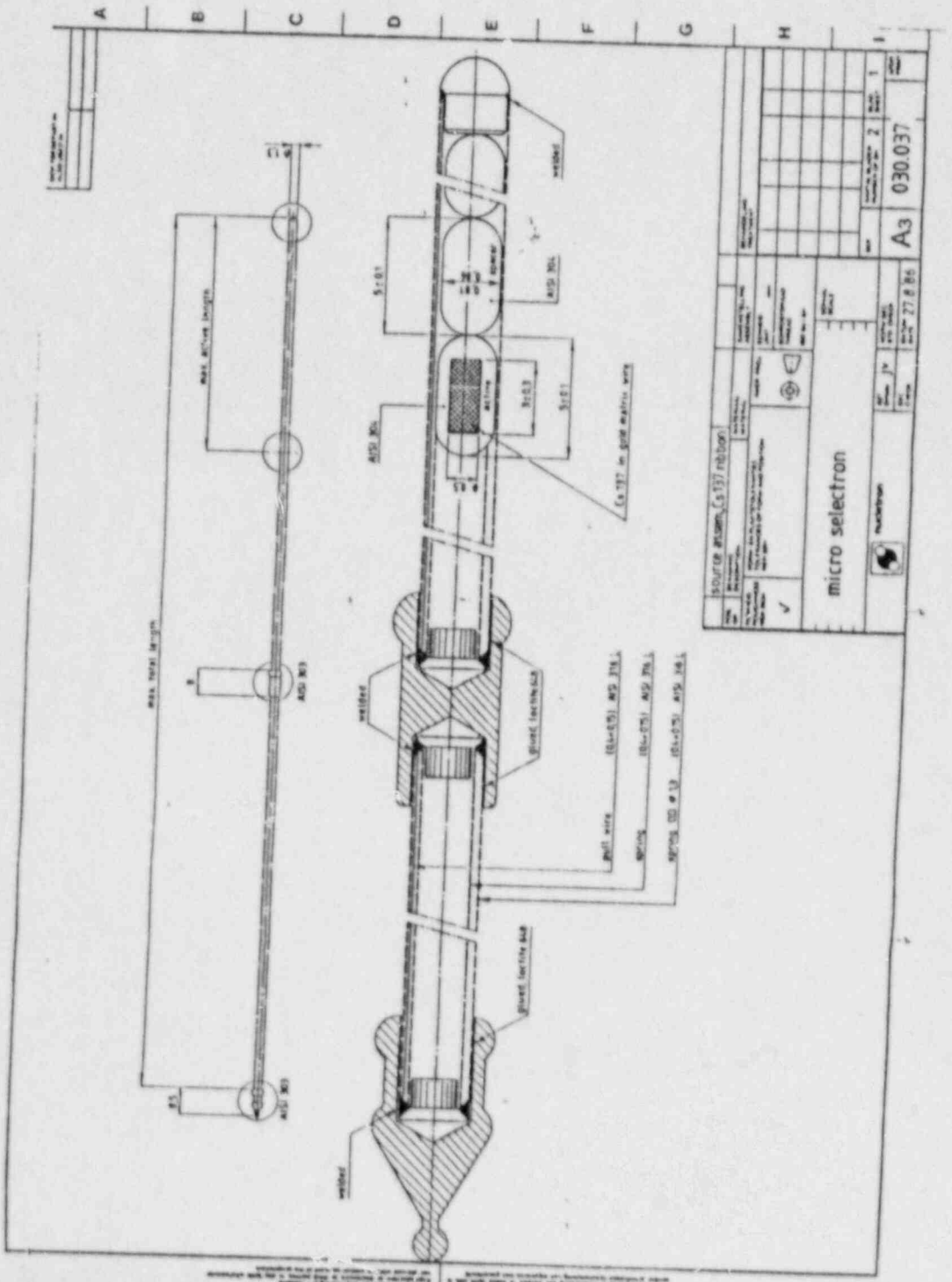
Item 6 a

DEVICE B

Device Type:	MicroSelectron Remote Afterloading Unit.
Manufacturer:	Nucletron Engineering, B. V. P. O. Box 110 3956 CP Leersum, Holland
Model Name/Number:	MicroSelectron/Model SEL-4000
Distributor:	Nucletron Corporation 9008 Red Branch Road Columbia, Maryland 21045 301-964-2249
Radionuclide:	Cesium-137
Sealed Source Manufacturer:	Amersham Corporation 2636 South Clearbrook Drive Arlington Heights, IL 60005
Model Number:	CDC - CY 14 (NOTE: Discussions are underway between Amersham, Nucletron, and USNRC regarding the assignment of this new Model Number for the sources used in the MicroSelectron; see attached drawing. Contract Steve Baggett, Materials Certification & Procedure Branch; Division of Fuel Cycle & Material Safety for information) We will use a permanent inventory of 270 Cs-137 seeds in 40 source trains (st) assemblies; 4 st with 4 seed; 6 st with 5 seed; 7 st with 6 seed; 11 st with 7 seed; 5 st with 8 seed; 5 st with 9 seed; 2 st with 10 seed. Sources are not limited to one supplier or model number. Iridium wire or seeds encased in nylon ribbon may be adopted for supplemental use in the 5 remaining channels.
Maximum Activity:	Nominal 2.1 Curies of Cs-137; nominal 3 Curies of Ir-192.
Number of Sources:	45 total sources may be used; of those only 15 sources are used at any one time with the MicroSelectron; the remaining 30 sources are stored in an adjacent external shielded container. (NOTE: This device is listed in the NRC's "Registry of Radioactive Sealed Sources and Devices" as Number: MD-497-D-103-S, dated December 12, 1985.
Intended Use:	Medical Irradiator for interstitial and intracavitary treatment of human cancers.

Item 6a
June, 1987
Attachment: Device B
(Source Diagram)

DEVICE B
(SOURCE DIAGRAM)



U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 7 Medical Material for Medical Use

License No. 12-01087-07 grants the Medical Radioisotope Committee the authority to approve user of Group VI sources, if they possess proper certifications and experience.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 9

Instrumentation

No additional instrumentation (Survey Meters, Geiger Counters, etc.) others than those previously listed in the license application for License No. 12-01087-07 are required for use with either Device A or Device B.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 10 Calibration of Instruments (Source Calibrations)

DEVICE A

Source calibration shall be performed at each source exchange using one of the NBS traceable calibrated dosimeter systems available (see attached list of dosimetry equipment). A special alignment device will be used to position the chamber in air in fixed, reproducible distance from the source at a long distance relative to the source dimensions, to determine the exposure rate in air at a fixed distance from the source. The apparent source activity, in curies, will be derived and compared to the equivalent activity of the sources, as stated on the Vendor's Certificate (see attached example certificate).

Travel time error will be determined using the multiple timing/cumulative dose techniques commonly employed for measuring timer error for Co-60 teletherapy units.

Timer accuracy will be measured using an electronic stop watch with 1/100 second precision. Qualifications of individuals performing calibration meets criteria in 10 CRF 35-24 (a) and (b).

DEVICE B

The initial activity of the permanent inventory of Cs-137 source trains will be specified by the source manufacturer.

The activity of any supplemental Ir-192 sources used will be specified by the Ir-192 source manufacturer.

As the unit is a low dose rate device, with therapy sessions of 2 to 4 days duration, there is no necessity for timer error measurements.

Elapsed time accuracy will be measured with an electronic stop watch with 1/100th second precision. Qualifications of individuals performing these checks meets criteria 10 CFR 35-24 (a) and (b).

Item 10
June, 1987

Attachment: Dosimetry Equipment List

Hines VA hospital Dosimetry Equipment List
Prepared by G. P. Glasgow, Ph.D.

GPG
6/87

SYSTEM	ELECTROMETER/CHAMBER	LAST CALIBRATION DATE	ENERGIES	CALIBRATION FACTOR	STATUS	LOCATION	CALIB. WITHIN 2 YRS ?	NEXT CALIB. DUE
R/NEL	Keithley 616/6169; SN 134696/14395	2/24/84	Co-60:	4.741×10^9 R/C				
	NEL 2505/3A, SN.1546 (0.6cc graphite; Acrylic Cap)	2/24/84	-	1.004	Weekly Betatron Calibr.	Betatron	No	Now
R/PTW	Keithley 616/6169; SN 134696/14395	2/24/84	-	1.004				
	PTW N23333, SN 514 (0.6cc acrylic; Acrylic Cap)	1/22/86	Co-60:	5.389×10^9 R/C	Not Used	?	Yes	1/22/88
			0.66Cu	See Report	"			
			2.95Al	See Report	"			
V/V	Victoreen 500-1; SN 432	9/25/85	-	1.001 C/RDG	Not Used	?	Yes	9/25/87
	Victoreen 555-100 MA (0.1mm, Delrin); SN 478	9/25/85	Co-60:	3.287×10^{10} R/C	Not Used	?	Yes	5/25/87
	Victoreen 555-100 MA (0.1mm, Delrin); SN 208	9/26/85	0.66Cu	See Report	Not Used			
			2.95AL:	" "				
			1.78AL:	" "				
VR/VC	Victoreen R-Meter 570; SN 1409;	7/26/81	See Report					
	Victoreen Condensor Model 621; SN 562;	7/26/81	Co-60	0.988 R/rdg	Not Used	?	No	Now
	Victoreen Condensor Model 131; SN 1934;	7/26/81	0.27Cu:	1.002 "	"	?	No	Now
			3.17Al:	1.012 "	"	?		
C/	Capintec 192A; SN 63F285		-					
	Capintec PR-06 SNCII0.6772 (0.66cc Farmer, C552) with polysty cap		Co-60	1.00	Monthly Co-60 QA	Cobalt Room	No	Field Instrument
	Capintec PS-033; SN CII0.33689 (0.5ml - Thin W)							

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 18. Waste Disposal

DEVICE A

Spent sources will be returned to the supplier within six weeks following source transfers and replacement.

DEVICE B

Spent supplementary Ir-192 sources or decayed Cs-137 source trains will be either returned to the vendor following their use or disposed of as radioactive waste following the normal radioactive waste disposal practices at Hines VA Hospital, under the supervision of the Hines Radiation Safety Officer.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20a Facilities and Equipment

DEVICE A

1a. Device A is to be located in the existing Cobalt teletherapy room, D008-I. See the enclosed annotated drawing (1/4" = 1'). All walls of the teletherapy room contain concrete (147lb/ft^3). The north wall and west wall are against the earth; the south wall is a part of the adjacent betatron room maze and vault; the east wall forms the Cobalt teletherapy console (control) area and entry maze to the teletherapy vault.

The floor is a sub-basement floor which consists of 8" concrete slab resting on concrete support columns. There is no occupancy of the crawl space beneath the slab.

The ceiling is a 30" concrete slab 10' 9 3/4" above the floor. The area above the concrete slab is an outside entry way into the main hospital building and is an unrestricted area occupied only by those entering the main entrance of the hospital.

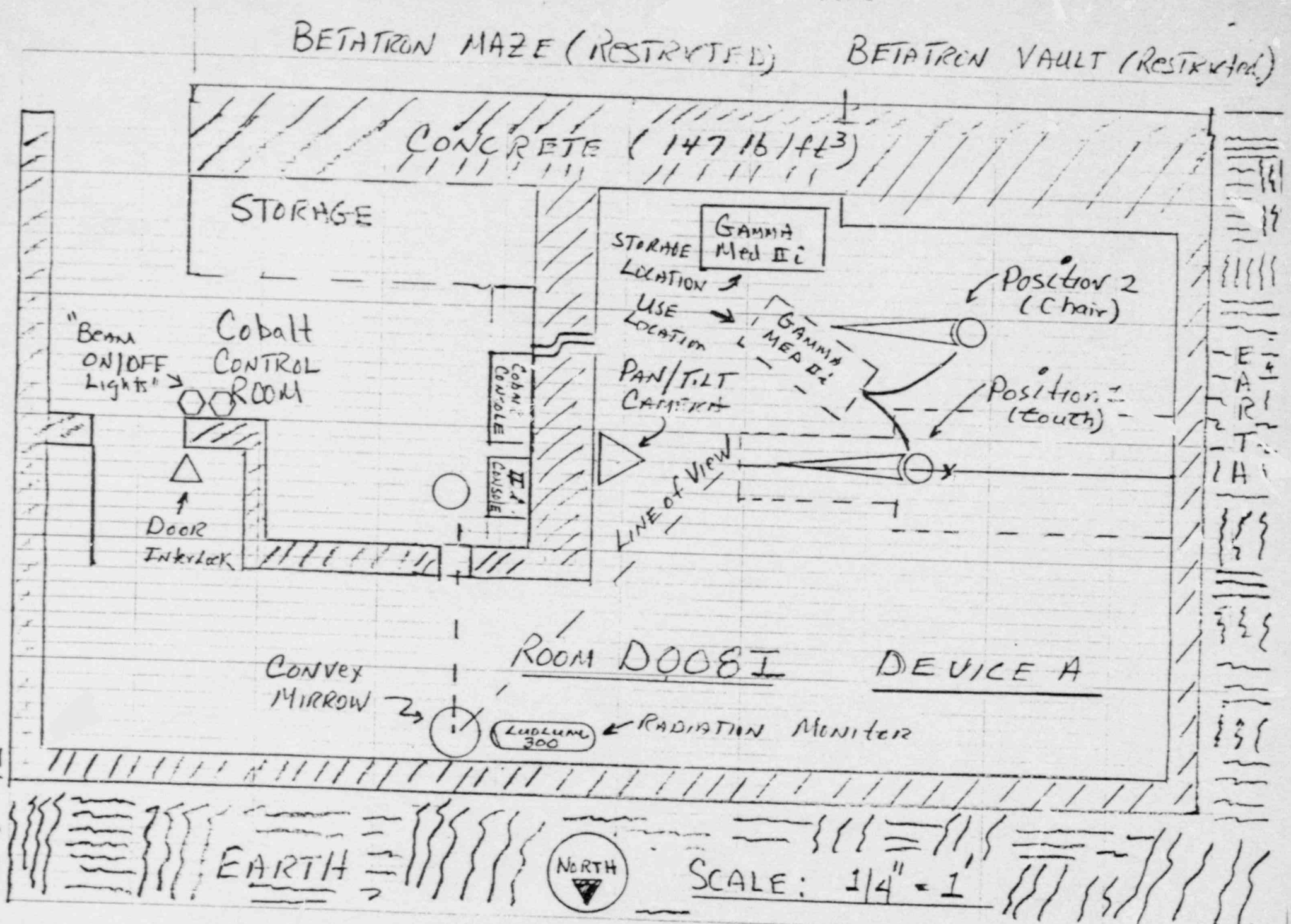
Device A, the Gamma/Med IIi Remote Afterloading System, is described in the attached Registry of Radioactive Sealed Sources and Devices (see attachments).

1b. Continuous Viewing of the patient is provided by direct observation via a window in the North wall of the Cobalt control room with a view of the room provided by a convex viewing mirror 18" in diameter. The remote viewing system consists of a pan and tilt TV camera with a zoom lens and a 9" TV monitor located at the control console. Both the direct and remote viewing systems allow the operator to observe the patients' under treatment either at position 1 on the existing Cobalt teletherapy couch or position 2, in a treatment chair.

1c. Area Security is maintained by a door interlock. Opening the door during therapy opens an electrical circuit causing the source to retract into it's protective housing. This door interlock and electrical circuit is physically independent of a similar door interlock and circuitry used for the Cobalt teletherapy unit. Once tripped, the door interlock must be reset before the Gamma MedIIi can be activated.

1d. Restricted Area control consists of a warning light (Beam ON - Beam OFF Lamp) mounted adjacent to the door and physically independent of the warning light associated with the Cobalt teletherapy unit.

1e. A Ludlum model 300 radiation monitor, electrically powered, continuously monitors the radiation environment in the Cobalt teletherapy vault, and is equipped with a back-up battery power supply for emergency operation. A flashing red light warns anyone present in the room that a sealed source is not in its protective housing, and that the radiation level at the monitor exceeds 0.2 mR/h.



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Item 20(a).

JUNE, 1987

6/87

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NY 453 D 201 S DATE: September 10, 1986 PAGE 1 OF 5

DEVICE TYPE: Remote Afterloading Brachytherapy Irradiator

MODEL: GammaMed II-i

DISTRIBUTOR: Mick Radio-Nuclear Instruments, Inc.
1470 Outlook Avenue
Bronx, New York 10465

MANUFACTURER: Isotopen-Technik Dr. Sauerwein GmbH
Bergische Str. 16, D-5657 Haan
West Germany

SEALED SOURCE MODEL DESIGNATION: Dwg. No. GM 252.20-001
(Byk-Mallinckrodt CIL B.V.
1775 ZG, Petten, Holland)
Type A Shipping Container/Source Changer
Dwg. No. Tr131.05-000

ISOTOPE: Iridium 192
Depleted Uranium
(shielding)

MAXIMUM ACTIVITY: 10 Curies
6 millicuries

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) Medical Irradiator for treatment of human cancer

CUSTOM DEVICE: ____ YES __X__ NO

CUSTOM USER:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NY 453 D 201 S DATE: September 10, 1986 PAGE 2 OF 5

DEVICE TYPE: Remote Afterloading Brachytherapy Irradiator

DESCRIPTION:

The Remote Afterloading Irradiator is a mobile unit designed to provide a predetermined dose to tissue by means of a Radioactive Source traveling through an applicator guide tube at preset incremental movement and dwell time. The Irradiator can be provided with up to twelve guide tubes, through which the single source is sequentially indexed. The Irradiator consists of:

1. The carriage, which holds the shielded source housing, emergency battery power supply, electronic controls and motors to actuate the source.

2. The source housing containing the Uranium and Tungsten shielding for the "OFF" or storage position is mounted on an extendable column by which the height of source guide tube can be adjusted within the range of 75 centimeters.

3. Separate Operator Console, with treatment progress CRT display and with hard copy printer, which enables the operator, located outside of the treatment room, to control and monitor the status of the Irradiator's operations.

The Irradiator's emergency battery power supply can enable the operator to retract the source into the "OFF" position in case of power failure. A secondary emergency procedure allows the operator to enter the treatment room, insert a hand crank into the source housing and manually retract the source into the "OFF" position. In case this manual retraction cannot be accomplished the last resort consists of pulling out the guide tube and inserting the source into an emergency lead shielded container.

LABELING:

The Irradiator is labeled in accordance with the provisions of the State of New York Industrial Code Rule 38, "Ioninizing Radiation Protection".

DIAGRAM:

See Attachments

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NY 453 D 201 S DATE: September 10, 1986 PAGE 3 OF 5

DEVICE TYPE: Remote Afterloading Brachytherapy Irradiator

CONDITIONS OF NORMAL USE:

The GammaMed II-i Remote Afterloading Brachytherapy Irradiator is intended to be used in the treatment of tumors by the application of ionizing radiation under the supervision and in the physical presence of physicians or medical technologists who were trained and certified by Mick Radio-Nuclear Instruments, Inc.

PROTOTYPE TESTING:

Prior to the introduction to the United States the Irradiator (an earlier Model) was used succesfully in Europe for 10 years without any significant malfunctions which could be attributed to design problems. TUV Rheinland Laboratory for medical technology in West Germany has tested the Device and has issued a seal of approval. The State of New York, Department of Health, Radiological Health Advisory Committee also evaluated the Irradiator (earlier Model GammaMed II) and found it to be safe and effective. The Sealed Source used in the Irradiator was tested and approved for the use by the Bundesanstalt fuer Materialpruefung (Federal Institute for Material Testing). The source was tested and found to comply with all applicable Regulations and Standards including the requirements of IAEA Special Form and ISO/C 53211 classification.

EXTERNAL RADIATION LEVELS:
Maximum radiation levels around the shielded source housing with 10 Curies of Iridium 192 source in the "OFF", retracted position.

Distance in Centimeters	Exposure in milliroentgens
5	2.8
30	0.45
100	0.10

QUALITY ASSURANCE AND CONTROL

The manufacturer submitted procedures acceptable to the Department.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NY 453 D 201 S DATE: September 10, 1986 PAGE 4 OF 5

DEVICE TYPE: Remote Afterloading Brachytherapy Irradiator

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

The Irradiator shall be distributed only to persons specifically licensed.

The Sealed Source shall be leak tested at periods not exceeding six months pursuant to Industrial Code Rule 38, Section 38.26.

Handling, storage, use, transfer and disposal shall be determined by the licensing authority.

The Sealed Source, except when utilized during the normal course of operations, shall be handled during service and source exchange only by persons specifically authorized, trained and certified by Mick Radio-Nuclear Instruments, Inc.

Prior to engaging in the application of Radioactive Materials to humans the operator must perform the required tests to ascertain that the Irradiator is functioning properly and that all emergency procedures and equipment are operable and in place.

The Irradiator shall be installed and tested for proper operation of all systems prior to any application to or treatment of humans. Person installing the Device shall ascertain that all required labels, radiation levels and safety monitoring components are in place and operational. Installation shall only be performed by Mick Radio-Nuclear Instrument, Inc., or by other persons specifically licensed by the NRC or an Agreement State who were trained and certified by Mick Radio-Nuclear Instruments Inc.

SAFETY ANALYSIS SUMMARY:

Based on data and evaluations submitted to the Department the GammaMed II-i is acceptable for licensing to hospitals and medical institutions engaged in treatments of humans for conditions for which the irradiator was designed. Furthermore it can be ascertained that even under conditions caused by equipment or component malfunction, based on the size of the source, available emergency equipment and procedures and time to implement them, the operator under most adverse circumstances would not sustain a dose which could exceed limits specified in Industrial Code Rule 38, Section 38.21.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NY 453 D 201 S DATE: September 10, 1986 PAGE 5 OF 5

DEVICE TYPE: Remote Afterloading Brachytherapy Irradiator

REFERENCES:

This Registry is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this document:

A. His letters dated January 18, 1985 and June 16, 1986, signed by Felix W. Mick, with enclosures.

DATE: September 10, 1986 REVIEWED BY: George L. Kasyk
George L. Kasyk

DATE: September 10, 1986 CONCURRED BY: F. J. Bradley
Francis J. Bradley, Ph.D.

ISSUING AGENCY:

The State of New York, Department of Labor

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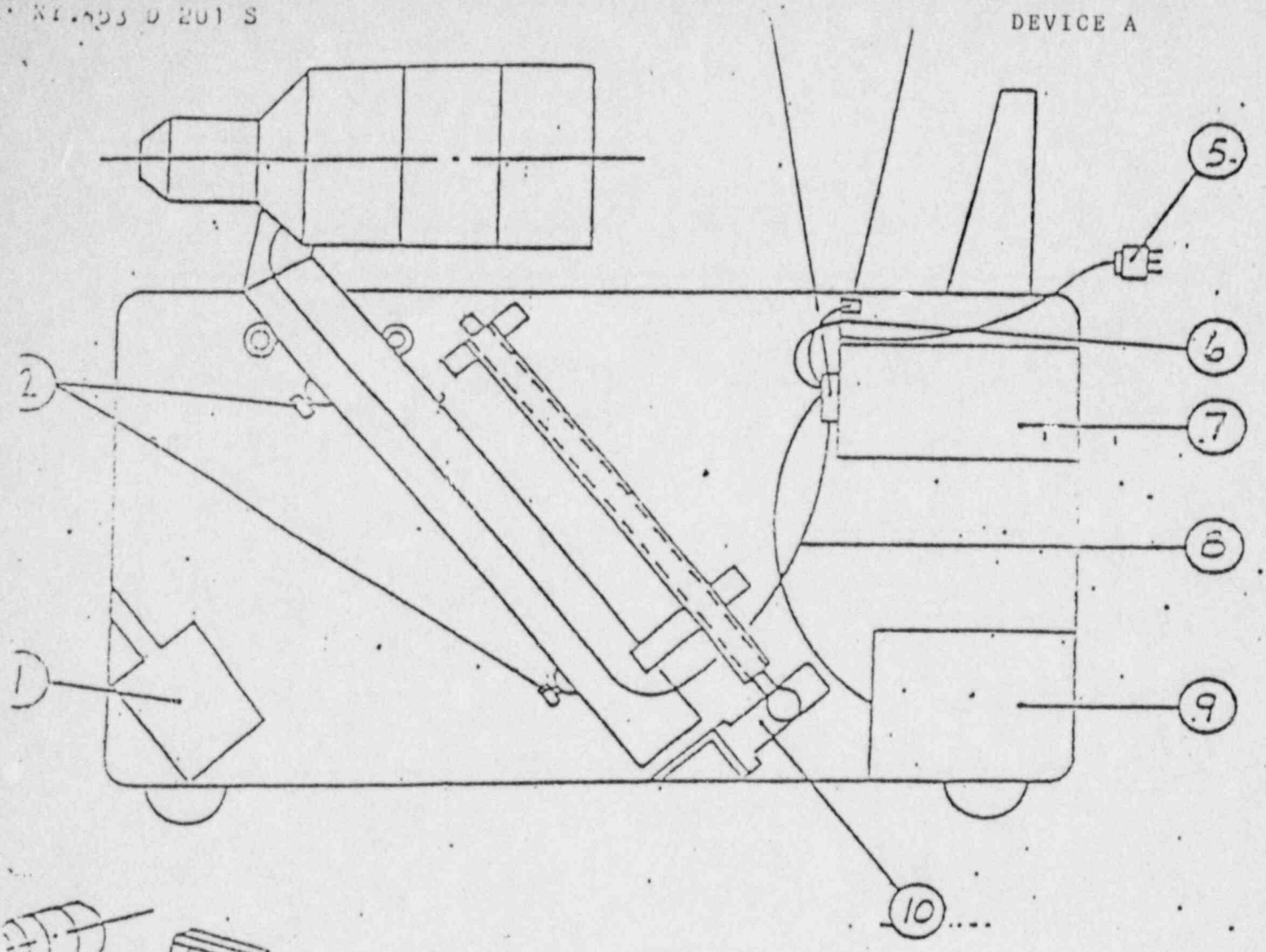
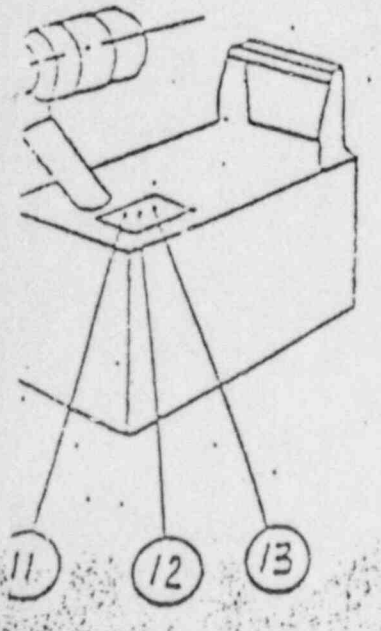
DEVICE A

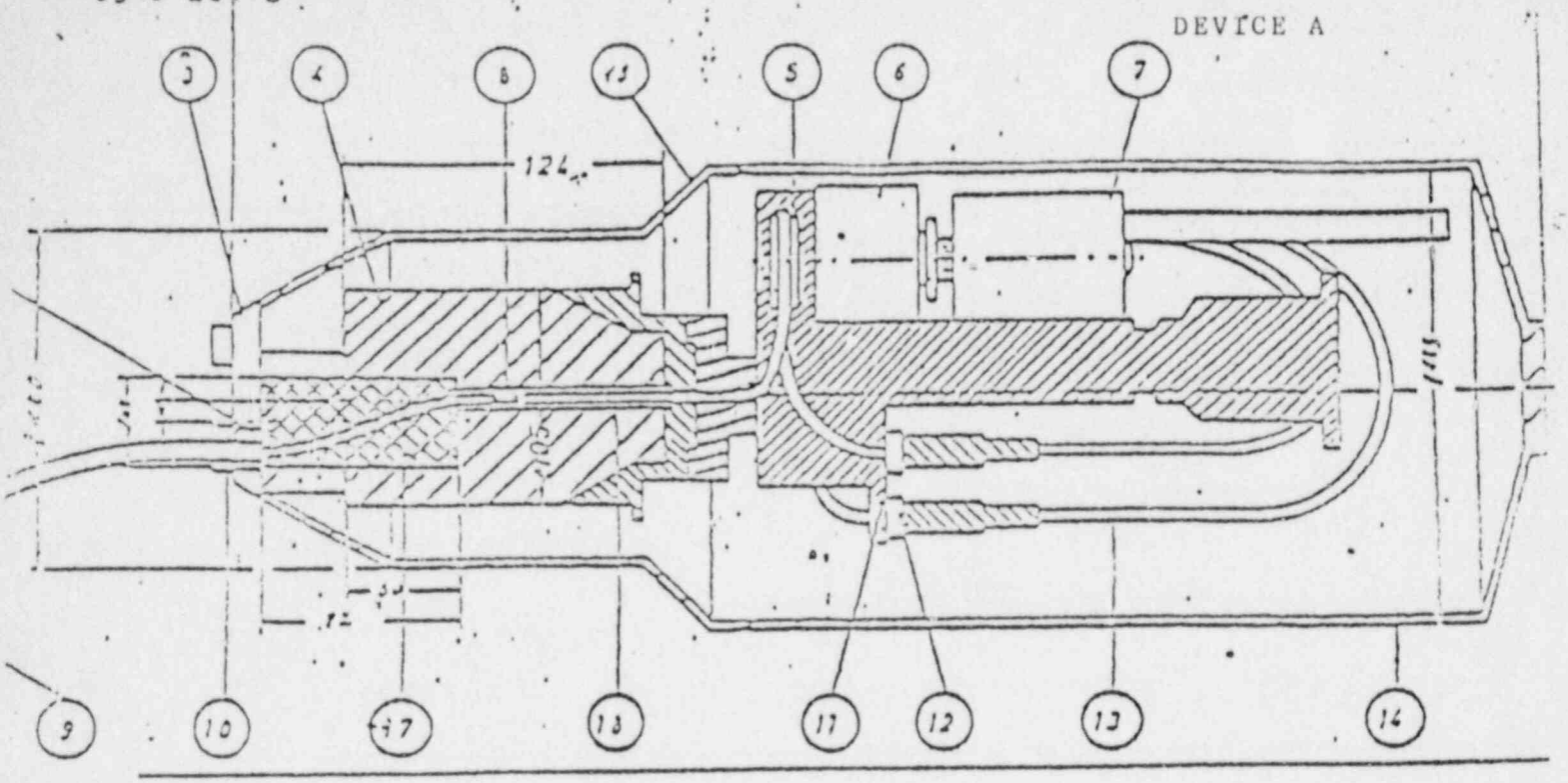


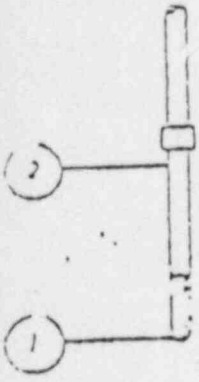


Gamma Med II

1	Lead container for emergency storage	8	Electrical cable
2	end switches	9	24 volt battery
3	Ventilator	10	Drive motor for Gamma Med head up or down mvts
4	Control consule electrical plug	11	Radiation warning light
5	120 v wall plug	12	Emergency source retractor button
6	fuses	13	Switch for GammaMed head up or down mvts.
7	Electronics		

DEVICE A



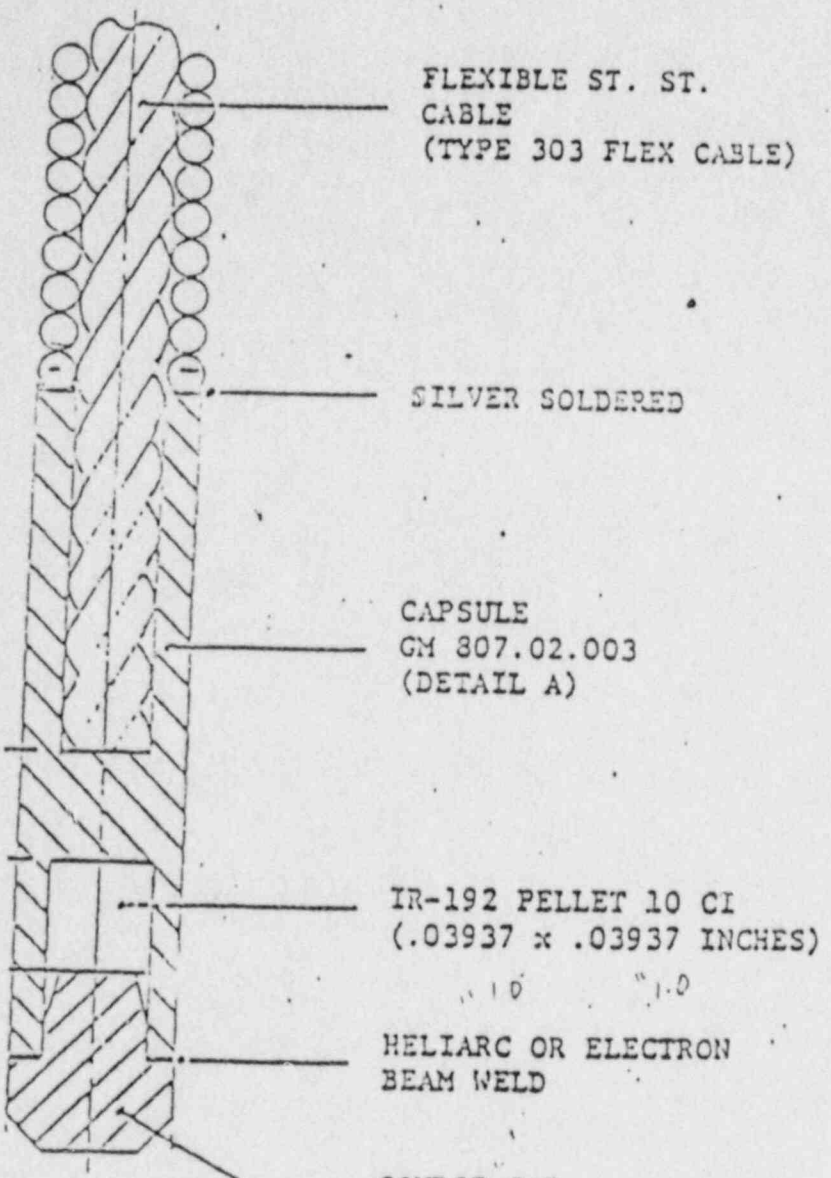


1	fixed limitation with source fully extended	6	drive motor
2	stainless steel tube applicator	7	emergency motor
3	turntable	8	source position w fully retracted
4	source container (depleted Uranium)	9	flexible guide tu
5	drive wheel	10	connector

11	limit switch "retracted"	16	limit switch
12	limit switch "extended"	17	S-channel tungst
13	storage tube	18	tungsten sleeve
14	cover PVC	19	stainless steel c
15	handcrank for emergency retraction of source		

Gamma Med II,
Source Housing

DEVICE A



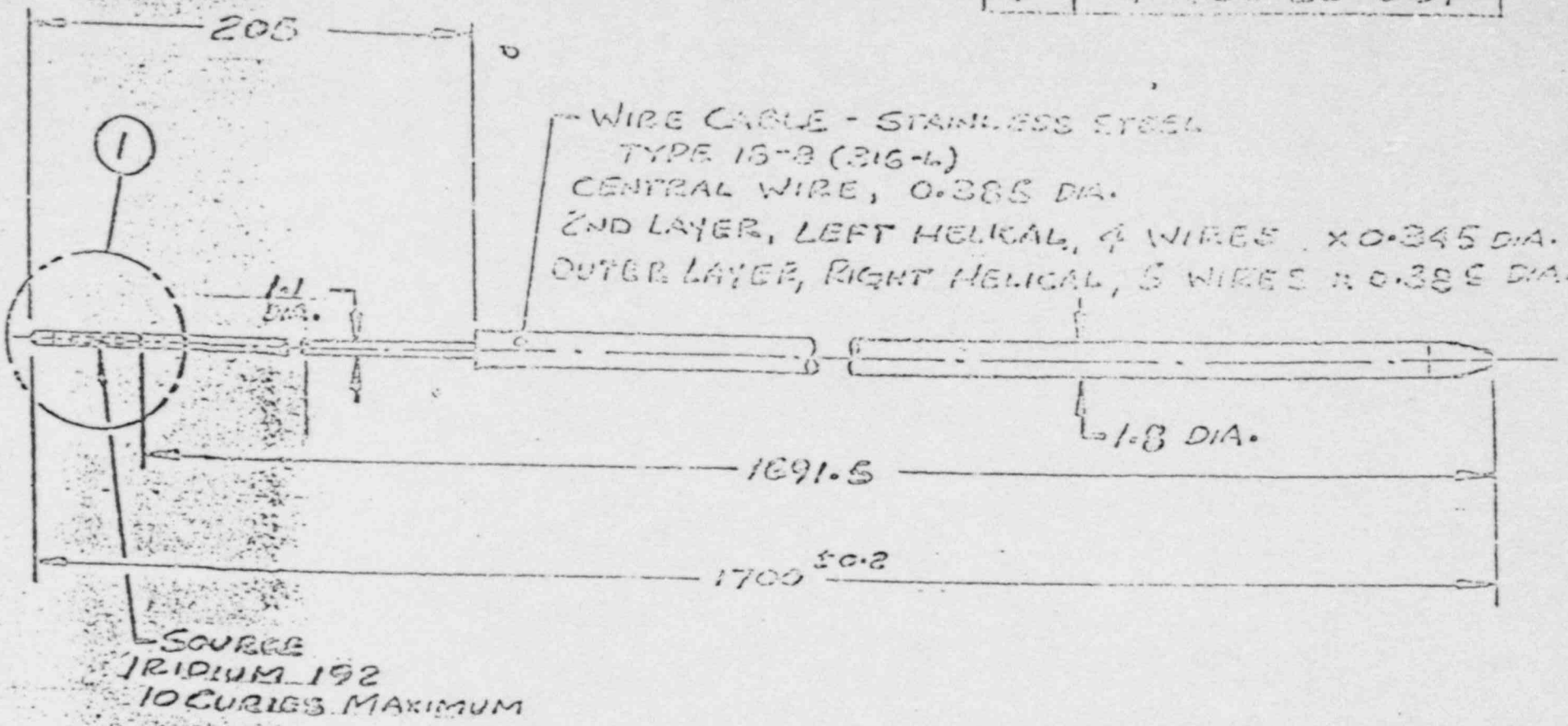
MATL: 18-8 (316L) ST.ST.

MICK RADIO-NUCLEAR INSTRUMENTS, INC

BRONX, NEW YORK

GAMMA MED
SOURCE CAPSULE ASSEMBLY

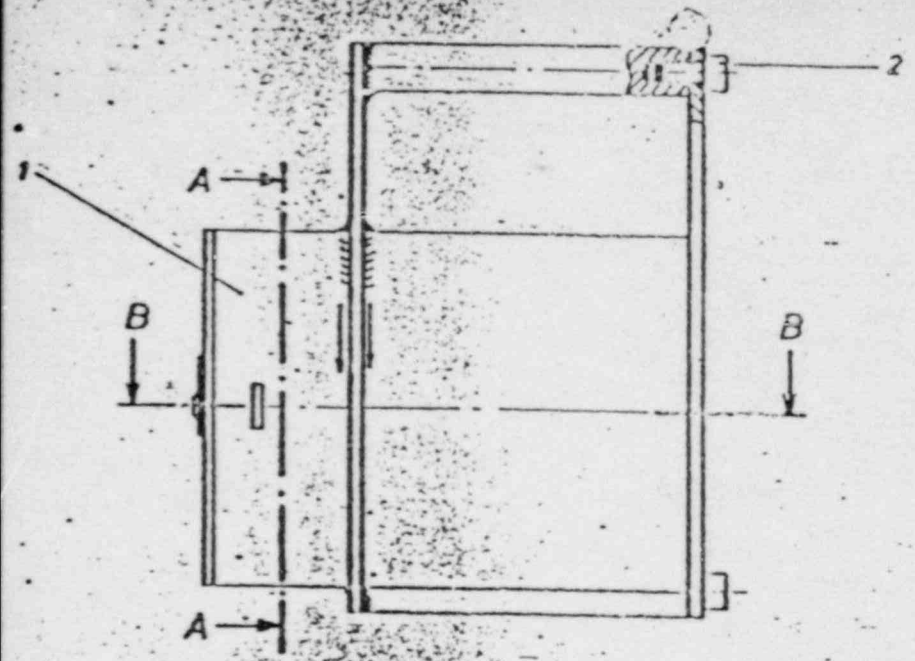
1	GM252-20-001

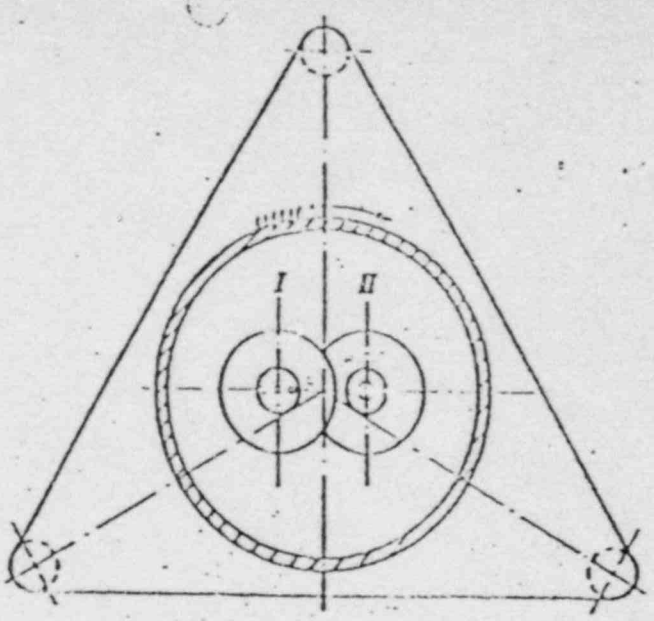


ALL DIMENSIONS IN MILLIMETERS

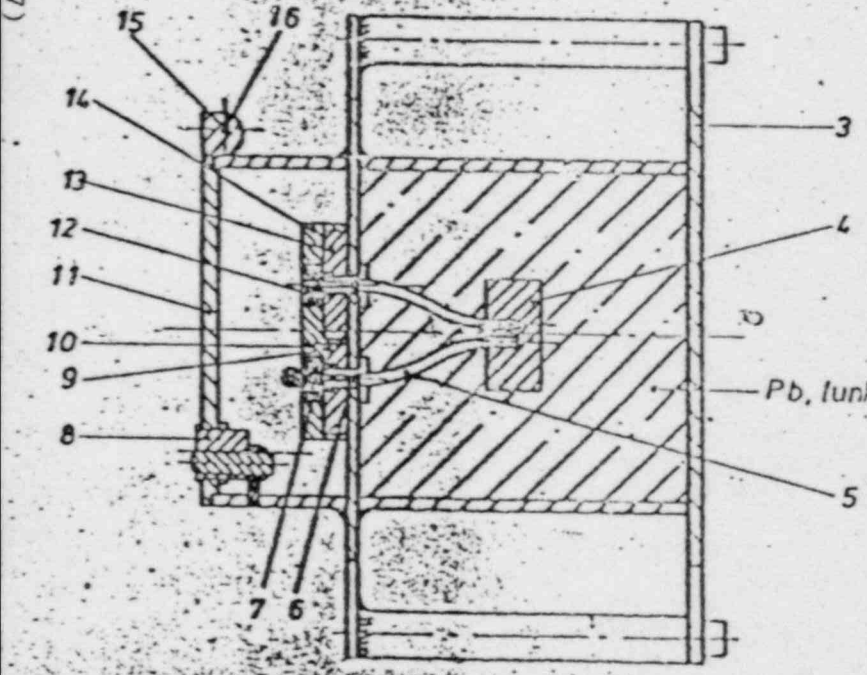
MTR.	FIN.
EXCEPT AS NOTED 3 DEC. ± .003 1 DEC. ± .030 2 DEC. ± .010 ANGLES ± 1	GAMMA-MED SOURCE CABLE
DO NOT SCALE DRAWING	DRAWN: K.Zelic 6-7-85 / CHECKED: / APPROVED: / NEXT ASSEM.
Mick Radio-Nuclear Instruments, Inc.	SIZE: / DWG. NO. GM252-20-012

NY 453 D 201 S





Schnitt A-A



Schnitt B-B

ISOTOPEN-TECHNIK
DR. SAUERWEIN GMBH
5657 HAAN

Maßstab 1:2,5

Bezeichnung:
Gamma Med
Transportbehälter

Zeichn. Nr.
Tr 131.02 - 1

Item 20a (Cont'd.) Facilities and Equipment DEVICE A

1f. Independent operation of Device A and the Cobalt teletherapy unit is assured by having totally separately operating consoles and a single key that activate each console, but only one key ring. Hence, the key must physically be removed from the Cobalt teletherapy console to activate the Gamma IIi console. Emergency replacement keys are kept in Room IF 334-W, in a separate building, and multiple console keys are not available to radiation therapy technologist operating these units, but are available to supervisory personnel.

1g. Shielding Evaluations.

The outside of North and West walls of the Cobalt teletherapy vault are backed by earth fill and cannot be occupied. Outside the South and East walls are restricted areas. The only area that can be occupied by the general public is the entry way to the main hospital, over the ceiling covering the Cobalt vault. For the Cobalt vault, and Device A, ssume that any patient treated would be placed no closer than about 0.5 meter from any adjacent wall and neglect any patient self-attenuation of radiation. The exposure rate 0.5 m from a 10.0 Ci Ir-192 source is:

$$\dot{X} = (4.6 R cm^2 h^{-1} mCi^{-1}) (10^4 mCi) (5 \times 10^1 cm)^{-2} \quad (1)$$

$$\dot{X} = 18.4 R h^{-1} @ 0.5 m \quad (2)$$

As the betatron maze wall is about 3 ft or 1m thick, from NCRP Report #49, pp. 102, the transmission through concrete is about 10^{-6}. Hence, the exposure rate in the maze is:

$$\dot{X} \text{ maze} = (18.4 \ R h^{-1})(10^{-6})(5 \times 10^1 cm / 1.5 \times 10^1 cm)^{-2} \quad (3)$$

$$\dot{X} \text{ maze} = 2.0 \times 10^{-6} Rh^{-1} \quad (4)$$

This is well within the limits required for this restricted area.

For the Cobalt wall about 2 ft thick (~0.67m), the wall transmission factor is 8×10^{-5}. The exposure rate in the Cobalt console area is:

$$\dot{X} \text{ cobalt} = (18.4 \ Rh^{-1})(8 \times 10^{-5})(5.0 \times 10^1 cm / 1.17 \times 10^1 cm)^2 \quad (5)$$

$$\dot{X} \text{ cobalt console} = 2.7 \times 10^{-4} Rh^{-1} \quad (6)$$

Item 20a
June, 1987

Item 20a (Cont'd.) Facilities and Equipment DEVICE A

This is less than 2 mR per hour and even with continuous operation of Device A, the cumulative exposure would be only 10.8 mR in 40 hours.

The floor-to-ceiling height is 10' 9 3/4" and the floor-to-top of the concrete slate is 13' 3 3/4" at the concrete slab's lowest elevation; hence, the slab is 2 1/2' (76 cm) for which the transmission factor is 4×10^{-5}. The source will be at a maximum height of 3' above the floor with the patient in either treatment location so the source will be 10' 3 3/4" from the top of the slab.

The exposure rate at the top of the slab is:

$$\dot{X} = (4.6\ Rcm^2h^{-1}mCi^{-1})(10^4 mCi)(3.12 \times 10^2 cm)^{-2}(4 \times 10^{-5})$$

$$\dot{X} = 1.89 \times 10^{-5}\ Rh^{-1}$$

Assuming continuous operation of the unit for forty(40) hours will yield a cumulative exposure at the top of the slab of 0.75 mR.

1h. Restricted Area for Device A, the door of the Cobalt vault, is posted with "Caution: High Radiation Area" and "Caution: Radioactive Materials" signs. The room is secured and locked after regular working hours and the key is kept in a key box away from the unit.

1i. Personnel Monitoring consists of quarterly thermoluminescent dosimeters for monitoring whole body dose equivalents and supplied by R. S. Landauer, Jr. Co.

1j. Annual Instruction of personnel in radiation safety per 10 CFR 19.12 is performed annually.

1k. Surveys of exposure rates around a typical Device A are attached.

DEVICE A

GAMMA - MED II - i

SOURCE HEAD

SOURCE: IR. 192

MAXIMUM ACTIVITY: NOMINAL 10 Ci.

SURVEY INSTRUMENT: VICTOREEN CALIBRATION DATE: SEPT. 1986

DATE: 3/10/87 SURVEYED BY: D. MICK

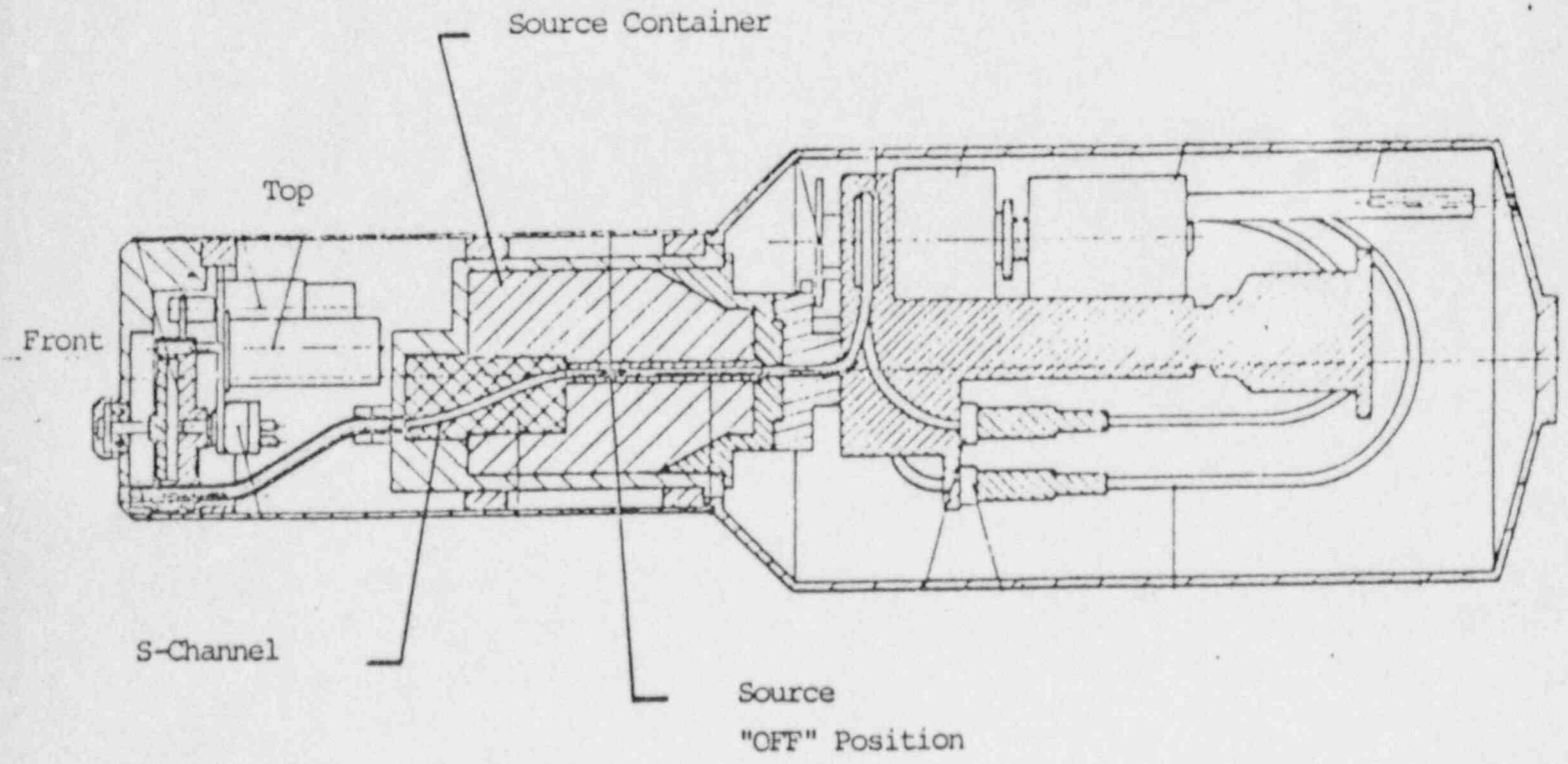
CUSTOMER: HENRY FORD HOSPITAL

ADDRESS: DETROIT

EXPOSURE RATE AT IRRADIATOR WITH SOURCE IN "OFF" POSITION:

TOP: 2.2 mR/hr.

FRONT: 0.4 mR/hr.



U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20a. Facilities & Equipment

DEVICE B

1. a. Device B is to be located in Room 741 W of Building 200. See the attached annotated drawing (1/4" = 1'). All walls of this room are conventional 6" thick plaster on both walls with no special or enhanced shielding capabilities. The North wall is an unaccessible pipe chase, toilet for the room, hallway to sink, and a wall adjacent to the lockers. The West wall is an outside wall. A portion of the South wall is adjacent to Room 740; with the remainder adjacent to the entryway to room 740. The East wall is adjacent to the hallway.

The floor is about 8" concrete slab and the layout of the room below, 641 W, and adjacent areas, is identical to 741 W.

The ceiling above is an 8" concrete slab and the layout of the room above, 841 W, and adjacent areas, is identical to 741 W.

The separation between floors is 12'.

Device B, the MicroSelectron Remote Afterloading Unit, is described in the attached Registry of Radioactive Sealed Sources and Devices (see attachment).

b. Continuous viewing of the patient is not required with this device; however, audible contact will be maintained via:

(i.) an intercom in the remote control unit outside the door;

(ii.) an intercom with a patient call button inside the treatment room.

(iii.) An audible and visual repeater system mounted at the Nurses Work Station.

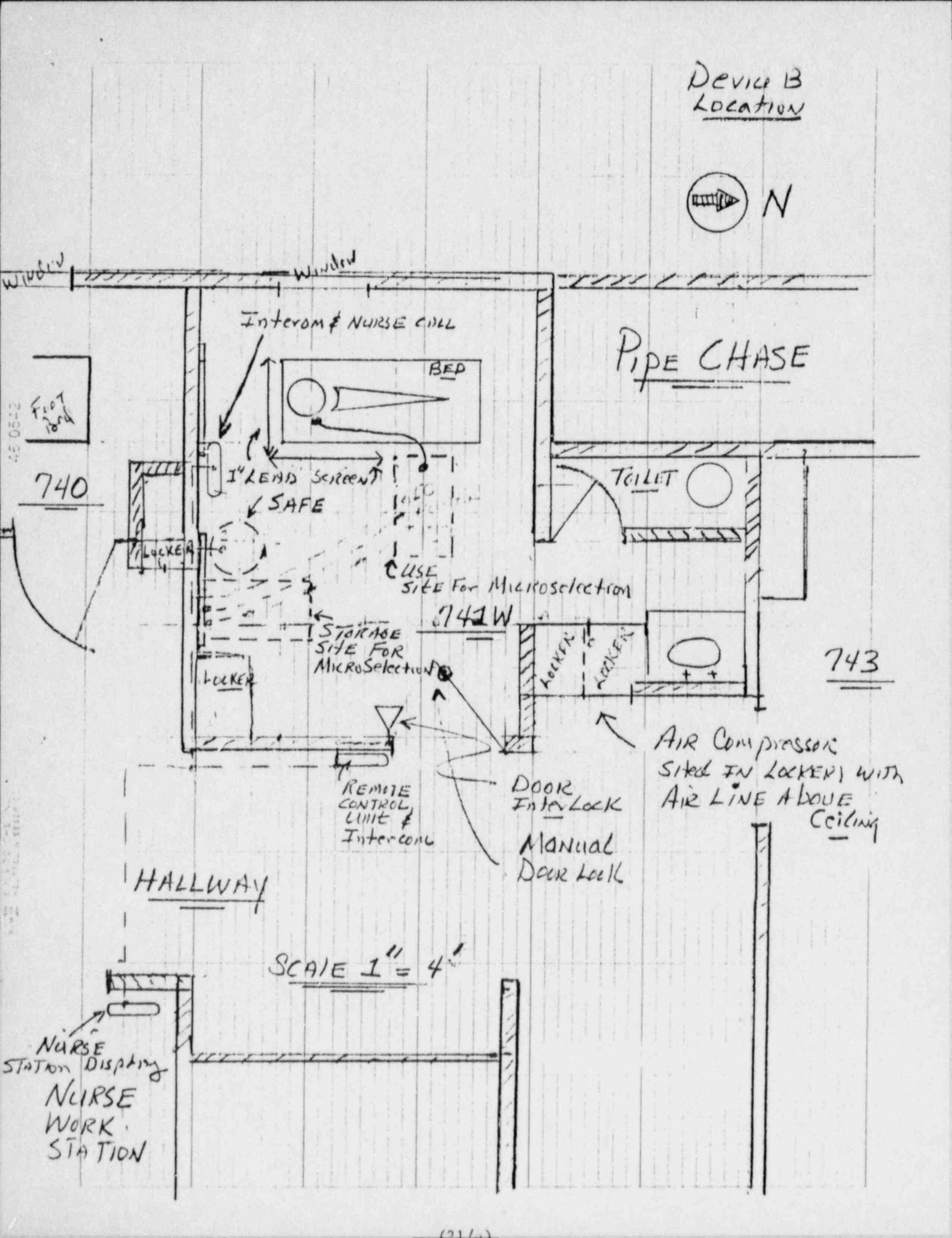
c. Area Security is maintained via a door interlock when the patient is receiving radiation and the sources are out of the safe. Opening the door during therapy opens an electrical circuit causing the sources to retract into the protective safe. Once tripped, the door interlock must be reset before the unit can be activated.

When Device B is not being used to treat a patient, it will remain in Room 741 W and the door will be locked and secured.

d. Restricted Area Control consists of a treatment "ON" light on the remote control unit mounted adjacent to the door. The light glows "Green" for a safe conditions, and "yellow" when treatment is in progress. Similar lights are on the nurse display station unit.

Additionally, the door of the Room 741W will be posted with "Caution: Radioactive Materials" and "Caution: High Radiation Area" Signs.

ATTACHMENT: Device B Location


Device B Location
N
Window
Window
Intercom & Nurse Call
BED
PIPE CHASE
740
1" Lead Screen
SAFE
LOCKER
TOILET
USE Site For Microselection
741W
Storage Site For Microselection
LOCKER
LOCKER
LOCKER
743
Air Compressor Sited in Locker) with Air Line Above Ceiling
Remote Control Unit & Intercom
Door Interlock
Manual Door Lock
HALLWAY
SCALE 1" = 4'
Nurse Station Display
NURSE WORK STATION

5. NRC S&D Registration and Review

MD-497-D-103-S MicroSelectron Remote Afterloading Unit

The following 7 pages are a copy of the registry review of the Selectron-LDR system, MD-497-D-103-S.

> **Note:** *The MicroSelectron uses the same iridium sources normally used by the Hospital. No change in ordering or delivery procedures needs to take place, although the MicroSelectron can enable the Hospital to re-use the sources.*

JAN 22 REC'D

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 1 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

Model SEL-4000

DISTRIBUTOR: Nucletron Corporation
9008 Red Branch Road
Columbia, Maryland 21045
Phone: (301) 964-2249

MANUFACTURER: Nucletron Engineering, B.V.
P.O. Box 110
3956 CP
Leersum, Holland

SEALED SOURCE MODEL DESIGNATION: Not limited to one supplier or model number. Iridium wire or seeds encased in nylon ribbon may be adapted for use.

ISOTOPE: Iridium-192 MAXIMUM ACTIVITY: 3 curies Iridium-192

LEAK TEST: Iridium-192 must be replaced at approximately 8 week intervals

PRINCIPLE USE: General medical use, interstitial treatment of cancer.

CUSTOM DEVICE: _____ YES __X__ NO

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 2 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

DESCRIPTION:

The MicroSelectron is a remote controlled afterloading system for treatment of cancer by interstitial placement of sources.

MAIN UNIT:

The main unit contains the control console, microprocessors, intermediate safe, fifteen drive motors and cables, power supply, battery backup, keyboard, display, and printer. The user can select any of 1 to 15 channels and a treatment timer. The printer lists all of the treatment data such as source assembly length, active length, position of external storage containers from which source was collected, treatment time, patient number, data and channels used. It will also list start and stop treatments and any alarm situations, together with the amount of treatment the patient has received and the time remaining. In case of power failure, the treatment is interrupted, the sources are returned into the lead intermediate safe within the main unit, all data is stored by battery back up and an alarm sounds. Since the source position within the applicator is checked by means of an air stream (as in the Selectron LDR and HDR) there is also a low pressure alarm in case of pressure failure, which will also result in the return of the sources to the intermediate safe in the main unit.

The main unit will collect the appropriate radioactive source assemblies from the external storage container and when connected to the patient, transfer these radioactive sources to the treatment position within the patient. All source movements to and from the main unit are initiated by the remote control unit located outside the treatment room.

REMOTE CONTROL:

The remote control unit located outside the treatment room is an independent microcomputer system which has a communication link with the master computer in the main unit. From the remote control unit the "start" and "stop" treatment signals are given. Further, it checks the condition of the door(s) to the treatment room and indicates the source position as being in the intermediate safe, in transit or in the treatment applicator and any failure situations. A resetable audible alarm is present.

An intercom enables the nurse at the remote control to communicate with the patient without interrupting the treatment. A key switch is provided that can restrict the use of the start-stop buttons and intercom to qualified persons. If the room door is opened during treatment, then the sources are immediately withdrawn from the patient into the intermediate safe in the main unit without the need of pressing the stop button. Contacts are available to connect and activate radiation warning signs during patient treatment. The remote control also contains the interface electronics for the remote nurse warning system.

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-3 DATE: 12/31/85 PAGE: 3 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

NURSE WARNING SYSTEM:

The nurse warning is an indicator panel both visual and audible that can be installed in the department nurse station. It has indicators for alarm situations, system in treatment, treatment interrupted, treatment time expired, and patient call.

EXTERNAL STORAGE CONTAINER:

The external storage container contains the supply of radioactive source assemblies manually placed in the container by staff or vendor personnel. It is the slave unit of the Main Unit of the MicroSelectron afterloading device. The external storage container is mounted on wheels so that it can be easily moved out of the way for storage, to a preparation area for manual insertion of new sources or to remove spent sources, or to the main unit to exchange radioactive sources. To collect a set of source assemblies from the 45 channel external storage container, the patient tube from the main unit is connected to the external storage container using the quick connect 15 channel coupling. A detection circuit in the main unit automatically switches to the source selection mode. Source selection is then carried out by means of 15 flexible tubes with safety connections which are attached to the storage container. An electronic detection circuit tells the main unit which of its storage container's 45 safes are connected to which storage area in the main unit and this data together with previously stored source details is provided for the treatment record.

To exchange the radioactive sources contained in the main unit, the sources in the main unit must first be returned to the storage container. The electronic detection circuit prevents transferring a source from the main unit to any storage container safe other than the one from which it originally came. Then the flexible transfer tubes can be attached to a different safe and different sources can then be transferred to the main unit.

PATIENT APPLICATOR:

Provided with the machine is a 15 channel quick-connector, a patient belt, and a supply of flexible and rigid treatment needles, and connecting tubes. The treatment needles are placed in the patient and attached to connecting tubes to the 15 channel quick-connector and thereby to the main unit. The quick connector enables the nurse to interrupt treatment by returning sources to main unit intermediate storage and then disconnect the patient from the afterloader by the quick disconnector to enable the patient to move about without removing the treatment needles from the patient. The connection of the patient tube to the quick connector is pneumatically locked during treatment and can therefore not be opened by the patient.

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 4 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

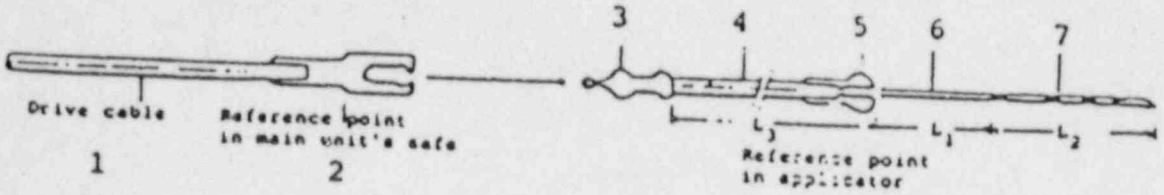
SOURCE ASSEMBLY:

Up to 45 source assemblies can be stored in the external storage container. The assemblies are alike in that they all have:

3. Male connector
4. Extension length (L3)
5. Control pellet
6. Inactive length (L1)
7. Active length (L2)

They differ in the length of the inactive length and active length, number of seeds, activity of seeds, and the spacing of seed sources in the active length. Refer to source assembly diagram. - Figure 1

The drive cable of the main unit has a female connector which attaches to the male connector of the source assembly, moves the source assembly from the storage container to the safe storage of the main unit and, as needed, moves the source assembly into the treatment needle and adaptor on a command initiated at the remote control. This system assures a position accuracy of better than 1 mm throughout the treatment.



1. Source transfer cable
2. Connector (female)
3. Connector (male)
4. Extension length L_3
5. Control pellet
6. Inactive length L_1
7. Active length L_2

Fig 1

LABELING:

An adhesive backed metallic electrical approval label is attached to the cover of the device where the electric cable enters the device. Two aluminum "Caution Radioactive Material" labels with the radiation trefoil symbol and specific radionuclide used in the system, are secured to the treatment unit; one label on the main unit and one on the storage safe. An aluminum adhesive label specifying the Selectron trade name and manufacturer's name is also attached to the base of the main unit and to the external storage safe.

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 5 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

CONDITIONS OF NORMAL USE:

The MicroSelectron is intended for all interstitial and intraluminal treatments of cancer using low dose. The procedure is identical to that of normal interstitial implant where the patient requires hospital nursing and treatment. The MicroSelectron eliminates or reduces the radiation exposure of hospital personnel. The system must be permanently installed in a shielded room when the temperature range does not exceed 5°C to 40°C. The system will be operated under the clinical direction of a radiotherapist but may be programmed by a trained medical physicist or technologist under supervision.

The normal useful life of the iridium sources would probably be two months.

The significant catastrophic condition that could occur would be fire although hospitals or clinics are normally built to meet local and national fire regulations. The lead shielding in the MicroSelectron is fully shielded in a steel envelope and it is not anticipated that the integrity of the shield would be impacted under these conditions. The system has been designed so that the sources can be withdrawn and the patient disconnected in approximately 5 seconds.

PROTOTYPE TESTING:

The MicroSelectron has been tested for the life of the drive motors, and nylon drive cables used to transfer the sources. The anticipated life of these components is greater then 10 years.

The MicroSelectron is similar to the Selectron LDR and the Selectron HDR in terms of the internal components, both mechanical and electrical. It is subjected to the same quality control checks and most of the data applicable to the Selectron HDR is also applicable to the MicroSelectron. There are approximately 10 MicroSelectrons now in use.

EXTERNAL RADIATION LEVELS:

When the main safe contains the maximum of 3 curies of Iridium-192 the dose rate within 10 cms of the surface is less than 0.25 mR/hr.

QUALITY ASSURANCE AND CONTROL:

Complete information on the manufacturer's quality assurance program of the MicroSelectron afterloading brachytherapy unit has been submitted to and deemed acceptable by Maryland.

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 6 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The device shall be distributed only to persons specifically licensed by NRC or an Agreement State.

2. Iridium sources will be replaced at approximately 8 week intervals.

3. Handling, storage, use, transfer, and disposal; to be determined by the licensing authority. Because the source assemblies must be assembled individually and manually placed in the storage container, the loading of the storage container must be done only by experienced, trained, and licensed personnel using adequate handling equipment and procedures.

4. The device shall be installed and initially tested for proper operation of the source exposure mechanism, safety warning component labels, and external radiation levels (both source exposed and source shielded) by a trained Nucletron service representative. Further, the reviewer should request documentation of training/experience of the service representative who will install and service the unit.

5. The device shall be installed in a shielded room that has adequate interlocks and labeling to meet the requirements of COMAR 10.14.02, Part D, Section D.203 or comparable NRC or Agreement State Regulations.

6. Because the connection made between the applicators and the guide tubes is critical to safety, the applicators used must be obtained from Nucletron.

7. This registration sheet and the information contained within the references shall not be changed without the written consent of the Maryland Department of Health and Mental Hygiene.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and data submitted, we conclude that the MicroSelectron device is acceptable for licensing purposes. We conclude that this device will be expected to maintain the containment integrity for both normal and accidental conditions which might occur during normal use.

REFERENCES:

The following supporting documents for the MicroSelectron are hereby part of this registry document:

Application for evaluation submitted by Nucletron Corp., 9008 Red Branch Road, Columbia, Maryland, 21045 under letter dated September 26, 1985.

REGISTRY OF RADIOACTIVE SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: MD-497-D-103-S DATE: 12/31/85 PAGE: 7 of 7

DEVICE TYPE: MicroSelectron remote after loading unit

ISSUING AGENCY:

This document is not a license to receive, possess or distribute radioactive material. Receipt, possession, and distribution of radioactive materials, sources, and devices containing radioactive material, are subject to terms and conditions of applicable regulations and licenses issued by NRC or Agreement States. Maryland Department of Health and Mental Hygiene.

DATE 1/7/86 REVIEWER Charles R. Flynn

DATE 1/13/86 CONCURRENCE Robert E Corcoran

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20a. Facilities & Equipment

DEVICE B

e. An additional, electrically powered, battery backed-up visual Area Radiation Monitor, independent of the MicroSelectron, will be used in the room to detect the presence of radiation in the event the MicroSelectron malfunctions. A constantly glowing light on the device will indicate that the sources have failed to retract into the MicroSelectron safe.

f. The MicroSelectron is key activated; the single key will be removed from the unit when it is not being used to treat patients, and the key will be stored at the Nurses Station. Emergency replacement keys will be kept in Room IF 334 W, in a separate building. Multiple keys will not be given to operating personnel.

g. The Radiation Survey of Room 741 W is described in the report (see attachment). The survey reveals 4 locations (E, K, L, and X) where the potential exists for exposures to exceed 2 mR in one hour or 100 mR in 7 days.

(i.) Location E was a point where leakage between the two lead screens occurs. With the current screens, the support bars precludes the screens from overlapping. Two new screens have been designed that will overlap to reduce exposure at this location.

(ii.) Location K and L are in a line-of-sight with the sources and adjacent to a hollow locker. An air compressor unit required to operate the MicroSelectron may be placed in this locker and could lower the hallway rates. Secondly, the MicroSelectron will be positioned by the bed and may provide some shielding for this point. Thirdly, a second bedside shield may be used for this location. The radiation exposure at this location will be reevaluated following siting of the MicroSelectron and the other components of the system and supplemental shielding used to solve this problem will be added, if necessary.

(iii.) Location X exposure rates will be reduced by the addition of an appropriate amount of lead to the bed in room 741 W.

In conclusion, Room 741 W can be used for the MicroSelectron, but attention must be given to the exposure rates at these locations during the actual use of the unit.

h. Restricted Area for Device B consists of the interior of Room 741 W; all adjacent areas will be unrestricted.

GPG
6/9 6/10, 1987

RADIATION SURVEY OF ROOM 741W
HINES VA HOSPITAL

1. Objective: To preform a radiation survey of Room 741W to identify any shielding requirements for sitting the MicroSelectron.

2. Sources used: 116.2 mg Ra eq of Cs-137 consisting of five sources of 7.47 mg Ra eq and 8 sources of 9.85 mg Ra eq from the Hines Cs-137 sources safe were used.

This activity is about equal to the total initial activity of 121.5 mg Ra eq of Cs-137 (270 seeds, each 0.45 mg Ra) ordered for the MicroSelectron.

Survey Instruments: (A) Keithley 36100 Survey Meter, SN.14878, Calibrated 3/31/87.
(B) Ludlum 14C, SN. 24992, Calibrated 3/31/87.

4. Calibration Check: Prior to the survey, each instrument calibration was checked by using a single source (7.47 mgRa) located at various distances from the meter.

Meter	$\dot{X}$ at 3 m (mRh^{-1})	$\dot{X}$ at 2 m (mRh^{-1})	$\dot{X}$ at 1 m (mRh^{-1})
Calculated $\dot{X}$	0.68	1.5	6.2
Ludlum	0.6	1.5	5.5
Keithley 36100	0.6/0.7	1.4/1.5	5.3/5.4

Both Meters agree with the calculated X within the accuracy and precision limits of each meter.

5. Source Position: Sources were positioned, unshielded, 12" from the headboard of the bed, on the midline of the bed. The mattress was 30" above the floor; this simulates the sources in a head and neck cancer patient. We anticipate the vast majority of our patients will be head and neck patients.

6. Shielding Arrangements: Following initial surveys of the adjacent areas, two 1" thick lead shields were positioned as shown. The bed was positioned 3' from the wall with a 40" wide shield placed 6" from the bed. An additional 36" wide shield was placed next to the bed. The shields were <u>not</u> in contact.

7. Exposure Rates: Exposure rates were measured at 1' (30 cm) from the walls, 30" above the floor, at designated points around the room. Reported rates are the average of the readings with the two meters; at most locations, the meters gave identical results. In the room above rates were measured 1' (30 cm) above the floor; in the room below rates were measured 18" below the suspended ceiling which is 8.5' above the floor, so these rates are 7' <u>above</u> the floor of the room below.

8. Worst case conditions: These rates represent the "worst case" or highest exposure rates likely to be found because:

a) Unshielded sources were used; during treatment patient self-attenuation will reduce exposure rate from 0% to 30%, depending on the site of implant and the relative position of the sources in the patient to the measurement point.

RADIATION SURVEY OF ROOM 741W
HINES VA HOSPITAL

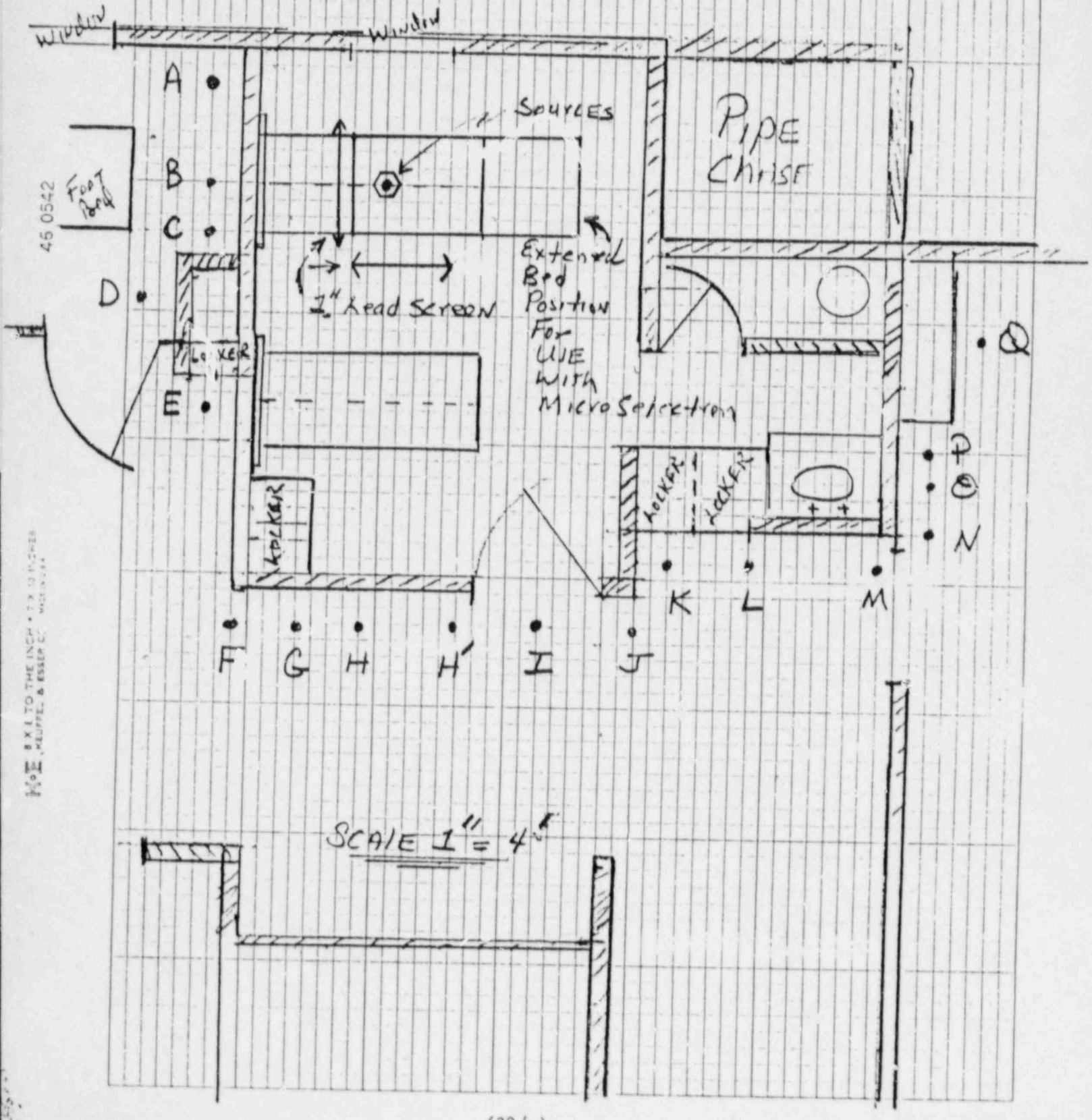
8. b) Maximum activity has been used; as only 15 of 40 sources can be used at the same time, the maximum activity of the 15 most radioactive sources with 126 seeds from theinventory of 40 Cs-137 sources, each with an activity of 0.45 mg Rq eq, is 56.7 mg Ra eq. This is 47%, or, of the total of 121.5 mg Rq eq in the permanent inventory and 49% of the 116 R mg Ra eq used for this survey. It is highly unlikely that more than 56.7 mg Ra eq would ever be used in a patient; this exceeds, historically, the maximum activity used in a patient, treating cancer in this anatomical site.

c) A typical implant will require treatment for 3 to 5 days; I haveassumed 5 days (120 hours) as the maximum use during a week of 7 days (164 hours).

GA
6/87

ROOM 741 W

(Points 30" Above Floor, 12" from Walls)



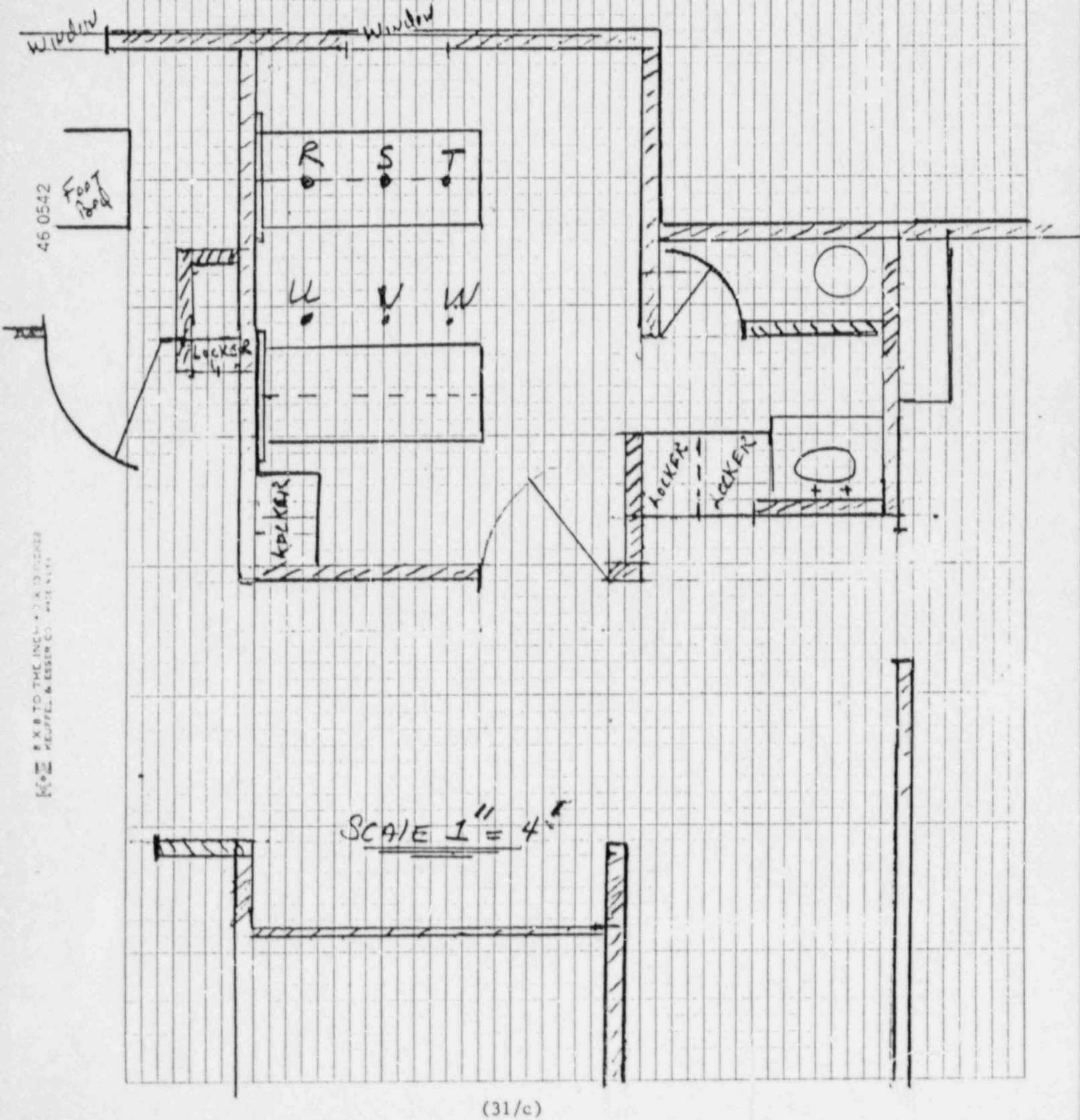
RADIATION SURVEY RESULTS

LOCATION	LOCATION DESCRIPTION	DATA USING 115.2 mg Ra eq			DATA USING 56.7 mg Ra eq		
		MEASURED X (mRh^{-1})	ESTIMATED EXPOSURE IN 1 HOUR (mR)	ESTIMATED EXPOSURE IN 5 of 7 DAYS (mR)	CALCULATED X (mRh^{-1})	ESTIMATED EXPOSURE IN 1 HOUR (mR)	ESTIMATED EXPOSURE IN 5 OF 7 DAYS (mR)
	ADJACENT ROOM 740						
A)	1' from S & W wall	0.55	0.55	66	0.27	0.27	32
B)	4' from W wall	0.65	0.65	78	0.32	0.32	38
C)	5.5' from W wall	0.60	0.60	72	0.29	0.29	35
D)	1' from locker wall; 7.5' from W wall	0.11	0.11	13	0.05	0.05	6.3
	HALLWAY						
E)	1' from LOCKER, W wall 1' from S wall	2.9 *	2.9 *	348*	1.41	1.41	170**
F)	0' from corner SE wall	0.30	0.30	36	0.15	0.15	18
G)	2' from corner SE wall	0.55	0.55	66	0.27	0.27	32
H)	4' from corner SE wall	0.55	0.55	66	0.27	0.27	32
H'	0.5 from edge of door	0.70	0.70	84	0.34	0.34	41
I)	center of CLOSED DOOR	0.65	0.65	78	0.32	0.32	38
J)	0' from corner NE wall	0.80	0.80	96	0.39	0.39	47
K)	1' from N wall	2.2 *	2.2 *	264*	1.1	1.1	129**
L)	4' from N wall	2.0 *	2.0 *	240*	0.98	0.98	117**
M)	7.5' from N wall	0.65	0.65	78	0.32	0.32	38
	ADJACENT ROOM 743W						
N)	0' from corner NE wall	0.35	0.35	42	0.17	0.17	20
O)	1.5' from corner NE wall	0.35	0.35	42	0.17	0.17	20
P)	2.5' from corner NE wall	0.35	0.35	42	0.17	0.17	20
Q)	2.5' from W	0.02	0.02	2	0.01	0.01	1
	ROOM 841W (ALL EXPOSURE RATES MEASURED 12" ABOVE FLOOR) (Directly above)						
R)	4' from W wall 1.5' from S wall	1.15	1.15	138	0.56	0.56	67
S)	4' from W wall 4' from S wall	1.10	1.10	132	0.54	0.54	64
T)	4' from W wall 6' from S wall	0.60	0.60	72	0.29	0.29	35
U)	8.5' from W wall 1.5' from S wall	0.30	0.30	36	0.15	0.15	18
V)	8.5' from W wall 4' from S wall	0.30	0.30	36	0.15	0.15	18
W)	8.5' from W wall 6' from S wall	0.25	0.25	30	0.12	0.12	15
	ROOM 641W (ALL EXPOSURES RATES MEASURED 18" BELOW CEILING, 7' ABOVE FLOOR) (Directly Below)						
X)	4' from W wall 1.5 from S wall	2.20*	2.20*	264*	1.1	1.1	129**
Y)	4' from W wall 4' from S wall	1.60	1.60	192*	0.78	0.78	94
Z)	4' from W wall 6' from S wall	0.70	0.70	84	0.34	0.34	41
AA	8.5' from W wall 1.5' from S wall	0.40	0.40	48	0.20	0.20	23
BB	8.5' from W wall 4' from S wall	0.30	0.30	36	0.15	0.15	18
CC	8.5' from W wall 6' from S wall	0.20	0.20	24	0.10	0.10	12

GPC
6/87

ROOM 841W

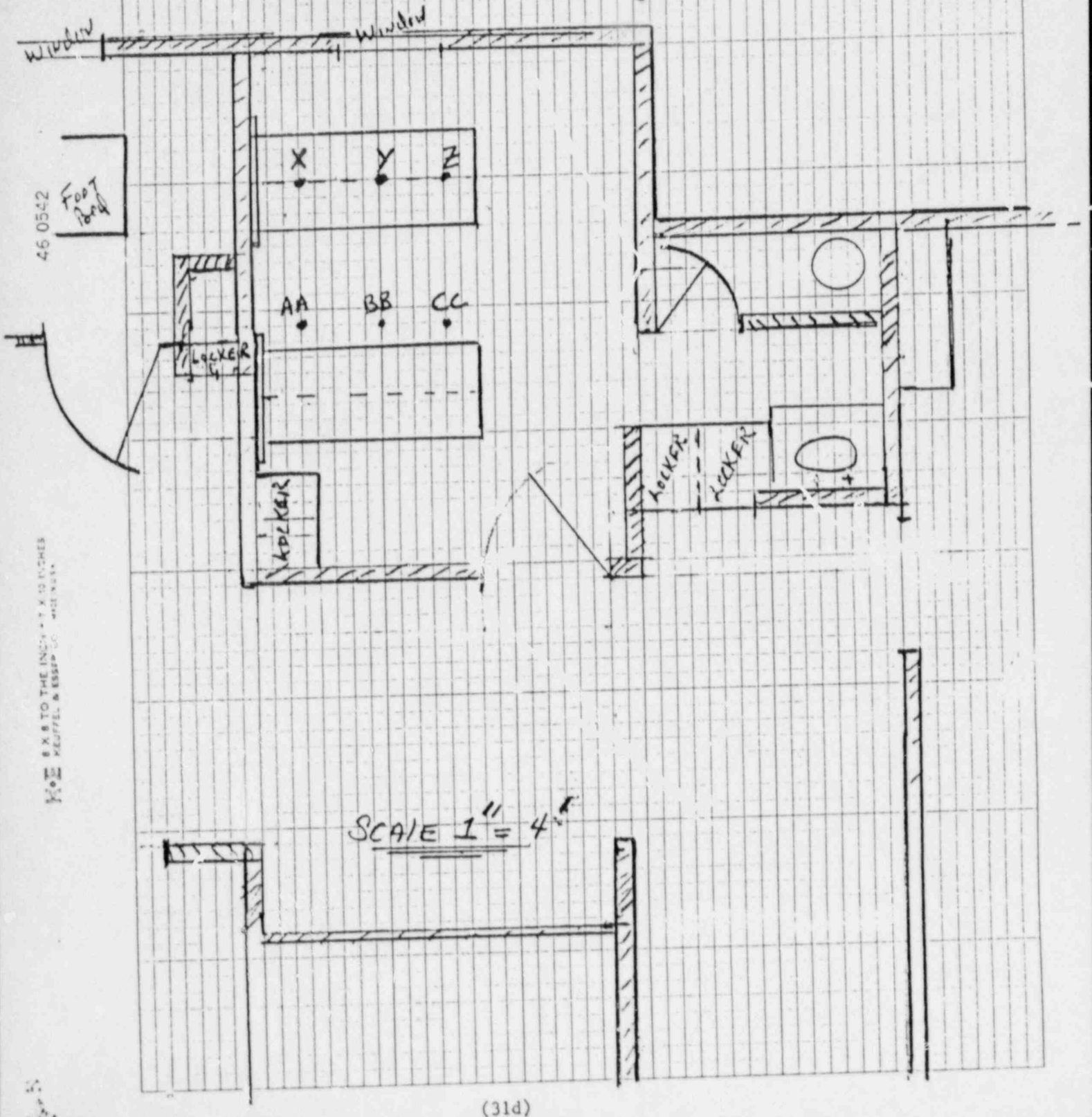
(Points 12" Above Floor)



GFA
6/87

ROOM 641W

(Points 18" below Ceiling, 7' ABOVE FLOOR)



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U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20a. Facilities & Equipment

DEVICE B

i. Personnel Monitoring consists of quarterly thermoluminescent dosimeters for monitoring whole body dose equivalents of personnel and supplied by R. S. Landauer, Jr. Co. The Nursing staff on 7 W is currently monitored.

j. Annual Instruction of personnel in radiation safety per 10 CFR 19.12 is performed annually.

k. Surveys performed by the Vendor of the MicroSelectron and mobile safe indicate that for 3 Curie of Ir-192, the exposure rate is 0.25 mR/h at 10 cm from the surface. As the Cs-137 tenth value layer and Ir-192 tenth value layer are almost identical, an equivalent activity of 4.3 curies of Cs-137 will yield the same 0.25 mR/h exposure rates at 10 cm. As we will have about 0.322 Ci total activity of Cs-137, exposure rates at 10 cm should be well below 0.25 mR/h.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20b. DEVICE A

1. a. Training of Individuals is outlined in the attached Training Course Outline, which is an all-day (8 hour) training session given to Radiation Therapy Technologists who operate the unit, and to other staff members (Physicians, Physicists Assistants, Dosimetrists) who have axillary responsibility for safe use of the device.

b. Source Exchanges are performed exclusively by trained personnel from Mick Radio-Nuclear, Inc.

c. Instructor of the initial training of individuals and of personnel exchanging sources is Felix Mick, president of Mick-Radio Nuclear, Inc. Subsequent training of new personnel not employed the time of device installation and retraining personnel will be provided by the trained senior members of the Physics staff and the trained Chief Technologist.

d. Device A Operation will be limited to those individuals who have satisfactorily completed the Training Course, including Emergency Procedures Practices.

e. Retraining of Personnel on Device A will occur at intervals not to exceed two years. The Retraining Course will include the following:

i. Review of control functions, including displays, menus, keys, buttons, printer, and emergency button use.

ii. Review of console operating procedures of data entry and responses to displayed machine parameters.

iii. Review of functions to be observed via closed circuit television prior to and during treatment.

iv. Review of medical procedures and axillary applicators used with Device A.

v. Review and practice of emergency procedures for several types of "failures" or emergencies.

Item 20b. (Cont'd.) DEVICE A

f. Operating Procedures for Device A are contained in an Operator's Manual, one copy of which will be located at the console controls; an additional copy will be available on site. Emergency Procedures for Device A will be conspicuously posted near the control console for operating personnel. The control console will be secured (off) and the operating key removed when not in use or when unattended.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20c. DEVICE A

Extremity dose equivalent for Device A will not be necessary as Device A operators do not handle sealed sources with Device A.

Mick Radio-Nuclear Instruments, Inc.

1470 Outlook Avenue, Bronx, N.Y. 10465

(212) 597-3999

GAMMA-MED II-i

"TRAINING PROGRAM OUTLINE"

I. GENERAL DISCUSSION : informal - open to questions and answers

1. Afterloading and Remote Afterloading

1.1 Explain the difference
1.2 Manual radioactive material handling as in implants, etc.
1.3 Remote Afterloading - no exposure...
1.4 History of Remote Afterloading at Memorial
1.5 Showing of slides - various HDR applications with Gamma Med system
1.6 Showing of 1/2" videos (VHS)
  a. original Memorial - Bronchus
  b. original Schumacher - Berlin - Brain, Breast, Bronchus
  c. Al Korba's - St. Mary's - Evansville, IN - Bronchus

II. HOW THE GAMMA-MED SYSTEM WORKS :

2. Source Travel
2.2 Stepping Distances
2.3 Dwell Times
2.4 Optimization

III. DESCRIPTION OF GAMMA-MED TROLLEY : On site

3. Power Supply 115V
3.1 Battery Storage 24V
3.2 Power Failure - Battery takeover
3.3 Source Head
3.4 Controls
  3.4.1 Elevator control - up/down
  3.4.2 Emergency button
  3.4.3 Radiation beam "ON" indicator
3.5 Source Guide Tube
3.6 Swiss Connector

June, 1987

TRAINING PROGRAM OUTLINE (cont'd)

3.7 Quick Connector
3.8 Indexer
3.9 Hand Crank
4.0 Pb Container

IV. SOURCE DRIVE MECHANISM & SOURCE SHIELDING : Removal of Protective Cover

4. Depleted Uranium Shielding
4.1 Tungsten shielding mechanism
4.2 Source drive mechanism
4.3 Stepping motor
4.4 Emergency motor
4.5 Encoder wheel
4.6 Photo electric sensors
4.7 Limit switches
4.8 Storage tubing

V. CONTROL CONSOLE :

5. Display screen
5.1 Menu
5.1.1 Menu - complete explanation
5.2 Keys - buttons
5.3 Printer
5.4 Emergency button

VI. ROOM SHIELDING :

6. Primary walls - 60cm concrete
6.1 Secondary walls - barrier
6.2 Door - Lead lined

VII. RADIATION SAFETY DEVICES :

7. GM Detector in trolley
7.1 Gamma Med "BEAM ON" Light box
7.2 Irradiation ON-CONTROL Panel
7.3 Door interlock - Deadman switch
7.4 Control console - Interrupt
7.5 Control console - Emergency
7.6 Restart - Program - Reset
7.7 Printer
7.8 Emergency Procedure (posted)

June, 1987

TRAINING PROGRAM OUTLINE (cont'd)

7.9 Radiation Alert - Auxilliary system
7.9.1 Short circuit camera for patient surveillance (with zoom)
7.9.2 Mirror
7.9.3 Intercom - Patient communication
7.9.4 Alarm - Gamma Med (acoustic)

VIII. IN CASE OF AN EMERGENCY :

8. Follow Instructions (Emergency Procedures Posted)
8.1 "Dry run emergency simulation"

IX. APPLICATORS / NEEDLES

X. DEMONSTRATION OF ACTUAL DUMMY SOURCE CABLE

XI. QUESTIONS - DISCUSSIONS

XII. TEACHING CONSOLE PROGRAM ENTRY ON AN INDIVIDUAL BASIS

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20d.

Transportation of sources for Device A from a storage site is not required as the source is contained in the treatment device.

Item 20e.

Source Accountability for Device A will be maintained via use records at the unit. The use record will, as a minimum, identify patient, date, source activity and the duration of treatment. Device A will be used only in the Cobalt vault and, with the exception of source changes, only one source will be available for use.

Item 20f.

Surveys during the treatment course with Device A are not required, as personnel will not enter the room during a normal treatment. The Ludlum 300 area survey monitor will be used to determine that the radiation levels in the room are safe following termination of a treatment. During treatments only the patient will be in the room, and all attending personnel will remain in the control area until treatment has terminated as indicated by both the control console and Ludlum 300 area radiation monitor in the room.

Item 20g.

Safety tests on Device A will be performed only on those days that patients are scheduled for therapy. With the source "ON", we will open the door and we will verify that the source reacts, the alarm sounds, and the printer reads; **DOR-Interrupt**. With the source "ON" we will verify the Radiation Alert Light on the console is "ON", the warning light above the door is "ON", and that the independent Radiation Monitor is "ON", and that the source indicator lamp on the console is "ON". With the source retracted, we will verify that, after opening the door, that the door light indicator on the console is "ON", but that the source cannot be activated.

Reproducibility of source positioning to within $\pm$1.5 mm will be checked monthly by viewing the transparent tube assembly via the closed circuit TV system. Selected time sequences will be checked monthly using a conventional electronic stopwatch reading to .01 of a second. Monthly, we will check that without a source guide tube attached, the source cannot be activated.

The emergency hand crank will be inserted into the source head prior to each use.

Source guide tubes will be inspected for imperfection prior to each use.

Calculated treatment time sequences will be verified via computer simulation, comparison to a standard dose atlas, or comparison to prior treatment sequences for identical therapy prior to each treatment.

Additional safety checks outlined in an attached list (see attachment) will be performed by the vendor changing the source at the time of source change.

Posted emergency procedures will include a current list of telephone numbers of individuals to be contacted in case of an emergency.

Item 20 g
June, 1987

MICK RADIO NUCLEAR INSTRUMENTS, INC. - SOURCE EXCHANGE PROCEDURE

C H E C K L I S T

RADIATION SAFETY TESTING ON GAMMA-MED II-i

CUSTOMER: _____

SERVICED BY: _____ DATE: _____

During regular maintenance service, the Gamma-Med Remote Afterloading system has been found in good _____ fair _____ poor _____ condition.

The following items have been checked:

	OKAY	FAULTY
1. Door Interlock with source in "ON" position and door is accidentally opened:		
a.) Source must retract automatically	_____	_____
b.) Alarm (acoustic sound) must go on	_____	_____
c.) Printer must read: DOR - Interrupt (retain copy of print-out)	_____	_____
2. Door Interlock: When door to treatment room is open:		
a.) Source can not be activated	_____	_____
b.) Door light indicator on console "ON"	_____	_____
3. Control Panel LIght Indicators:		
a.) Main Power Light	_____	_____
b.) Battery Power Light	_____	_____
c.) Source "ON" or "OFF" indicator light	_____	_____
d.) Guide Tube	_____	_____
4. Source must retract to "OFF" position at "0" time	_____	_____
5. The 2 Timers function properly (use stop watch)	_____	_____
6. During use of the afterloader: Emergency hand crank must be inserted into source head (key lock removed)	_____	_____

MICK RADIO NUCLEAR INSTRUMENTS, INC. - SOURCE EXCHANGE PROCEDURE

GAMMA-MED CHECK LIST / cont'd.

	OKAY	FAULTY
7. Without a Source Guide Tube attached, the source can not be activated	____	_____
8. When Source is in "ON" position:		
a.) The Radiation Alert Light on the control console is "ON"	____	_____
b.) The Light Box above the treatment room is "ON"	____	_____
c.) The independent Radiation Alert is "ON"	____	_____
d.) Source Indicator (red button) on control console is "ON"	____	_____

General Status on Safety Equipment:

9. Independent Radiation Monitor	____	_____
10. Audio and visual patient surveillance	____	_____
11. General order in treatment area	____	_____

12. Type and Model of Survey Equipment used:

Type: _____

Model: _____

Serial #: _____

Calibration Date: _____

Special Comments:

_____

_____

_____

SIGNED: _____

REMOVED SOURCE TAG

JUNE, 1987

Emergency procedures for Device A are to be carried out by the operator when the treatment must be aborted due to an equipment malfunction or an unforseen patient condition. In the event source retract fails, as noted on the closed circuit TV, and the source does not retract, the following emergency procedures attached will be carried out. (These procedures will be posted at the console.) A synopsis of the procedures follows: The manual interrupt will be activated. Next the treatment room door will be opened. If both of these methods fail to cause source retraction the operator will then enter the room and press the emergency button on the Device A. If this fails, the operator will use the hand crank to return the source to the shielded source container. If the hand crank fails tc operate, the source applicator tube will immediately be removed from the patient and placed in the emergency lead container on the front of the mobile irradiation device. All manual source handling will be done with long hand-held forceps. The in-room radiation monitor and a hand held survey meter will be used to confirm the source is properly restored or retracted. If the source cannot be returned to the irradiation device, the room will be secured after removal of patient and the access door locked. A sign will be posted indicating an unshielded source is present. The chief physicist and the attending physician will be notified. The physicist or attending physician will enter the room and locate the source, and place it in a lead pig (shielded container); Mick Radio-Nuclear will be notified, (212) 597-3999, and the source will not be used again until the malfunction is identified and repaired.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20b. DEVICE B

1. a. Training of Individuals is outlined in the attached Training Course Outline, Device B. The manufacturer's installation engineer provides on-site training in programming and operating the device, including emergencies procedures. This training is given to Physicists, Nurses, and Radiation Therapy Technologists, and other staff members (Physicians, Physicist Assistants, Dosimetrists) who will have responsibilities for safe use of the device.

b. Source Installation of the initial permanent inventory of Cs-137 source trains will be preformed by trained personnel from Nucletron Corporation.

Subsequent Source Exchanges of the inventory of permanent Cs-137 sources between the intermediate safe in the MicroSelectron safe and the adjacent external safe and of any Ir-192 supplementary sources will be performed by trained individuals in 'a'.

c. Instructor of the initial training of individuals in 'a' will be by of the individuals on the attached list of Nucletron Corporation Personnel. Subsequent training of new personnel not employed at the time of device installation and retaining of personnel will be provided by trained senior members of the Physics staff, trained senior members of the Nursing staff, or the trained Chief Technologist.

d. Device B Operation will be limited to those individuals who have satisfactorily completed the training course, including Emergency Procedures Practices.

e. Retraining of Personnel on Device B will occur at intervals not to exceed two years. The Retraining Course will include the following:

i. Review of control console functions, including keys, buttons, and emergency button use.

ii. Review of console operating procedures of data entry and response to displaced on drive parameters.

Item 20b.
June, 1987

Item 20b. (Cont'd.) DEVICE B

iii. Review of the functions to be observed at the remote console during treatment.

iv. Review of Medical procedures and axillary applicators used with Device B.

v. Review and practice of emergency procedures for several types of "failures" or emergencies.

f. Operating Procedures for Device B are contained in an Operator's Manual, one copy of which will be available at the remote console; an additional copy will be available on site. Emergency Procedures for Device B will be conspicuously posted near the remote console and adjacent to the door of the treatment facility. The control console will be secured (off) and the operating key removed when not in use or when unattended.

6.2 Qualifications of engineers and training personnel

The personnel listed below have been trained in the installation of the Selectron Remote Afterloading equipment and the loading of the radiation sources into the shielded lead safe of the Selectron from the transport container.

There are now 180 Selectron systems in 26 countries and people trained by Nucletron (the manufacturer of the Selectron) have been involved in every installation and commissioning of the equipment and in the training of technologists who operate the equipment.

Person	Years Experience	Experience and Training (Nov 1985)
L. van Zwol	10	Technical Director of Nucletron, responsible for design of Selectron equipment and quality control. Training in handling radiation sources given by Amersham International in Europe. [Amersham manufactures the radiation sources.] Also, "Ionizing Radiation" Level B (handling of Encapsulated Radio-Active Sources - IVBS Rotterdam).
R. Hermanus	5	International Service Manager of Nucletron responsible for worldwide warranty and service of the 175 Selectron systems. He has installed over 50 systems. Training, "Ionizing Radiation" Level B (handling of Encapsulated Radio Active Sources - IVBS Rotterdam).
M. Cragg	3	Service Manager, Nucletron. 30 installations of Selectron equipment and servicing in USA, United Kingdom and Canada.

Person	Years Experience	Experience and Training (Nov 1985)
C. Mellink	2	Trained by Nucletron (L. van Zwol and R. Hermanus). Has carried out installations in USA, Canada, China, Europe.
A.M. Mount	8	Nucletron Corporation, Columbia, Maryland. Physicist with 5 years background in handling radiation sources for medical and industrial use while working for Amersham in England, + two years experience with Nucletron in England where there are 30 Selectron systems, and 2 years in North America where there are 30 Selectron systems.
M. Gribble	10	Joined Nucletron September 1985. Medical Physicist who was advisor for the 11 Selectron systems used by the Ontario Cancer Foundation in Canada. Training by R. Hermanus and M. Mount. Previous radiation physics experience in United Kingdom, USA and Canada.

NUCLETRON CORPORATION

By:_____
A.M. Mount
President

JUNE, 1987

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20c.

DEVICE B

Extremity dose equivalent dosimeters for Device B will not be necessary as Device B operators do not handle sealed sources with Device B. They only connected sealed sources in well shielded safes to mechanisms that remotely remove the sources from the safe; no direct source handling occurs with this unit.

Only staff members manually preparing supplemental Ir-192 sources for use with Device B need wear extremity dosimeters.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20d. DEVICE B

Transportation of sources for Device B occurs only with supplemental Ir-192 seed or wire sources; these are transported using conventional, well-shielded transporters (carriers).

Item 20d.
June, 1987

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20e. DEVICE B

Source Accountability for Device B will be maintained via use records at the unit. The use record will, as a minimum, identify the patient, the date, the number, type and activity of Cs-137 permanent inventory sources, the number, type, and activity of any supplementary Ir-192 sources, and the duration of use of each source. Device B will be used only in Room 741 (West) of Hines VA Hospital.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20f. DEVICE B

For Device B, Surveys of the dose equivalent rate at 1 m from the patient will not be made as this requires defeating the door interlock to allow the surveyor to enter the room with the sources out (Unit "ON"). During routine use the sources will be retracted into one MicroSelection Unit's safe when someone enters the room.

Adjacent area surveys will be performed to ascertain that adjacent areas remain unrestricted areas.

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Item 20g. DEVICE B

Safety tests on Device B will be performed only on those days that patients are scheduled for therapy, with the device "on" during a test treatment. We will verify that main, remote, and Nurse display console lights functions; that all timers functions, and that "treatment", radiation "on", and "safe" lights functions, and that sources retract at the end of the test treatment sessions. The door interlock will be tested to verify that opening the door interrupts treatment and retracts sources into the safe and that the device will not come back "on" without being properly reset. (See attachment).

Accuracy of the desired sources positions to within I/1.5 mm will be checked by inspection of an auto radiograph taken during the test treatment.

Source guide tubes will be inspected for imperfections prior to each use.

Attached Safety Checks will be performed by the vendors service personnel at recommended intervals during the regularly scheduled servicing of the unit, or by in-house bio-electrical engineers. Who have received training on how to perform recommended servicing of the device.

Posted Emergency Procedures will include a current list of telephone numbers of individuals to be contacted in case of an emergency and list corrective actions to be taken in the event of ALARM conditions (see attachment).

Item 20g.
June, 1987

Attachment: On-Site Training -MicroSelectron-LDR

nucletron®

Nucletron Corporation

On-Site Training - MicroSelectron-LDR

The following operational sequences are covered by the on-site training scheme, and are delivered by the Nucletron installation personnel:

1) General system description
2) Treatment unit initialization
3) Source transfer (transport container to mobile storage safe)
4) Source inventory entry
5) Source transfer (mobile storage safe to treatment unit safe)
6) Programming of treatment unit
7) Handling and interconnection of applicator systems with treatment unit
8) Patient treatment sequence
9) Treatment completion and applicator reclamation
10) Source transfer (treatment unit safe to mobile storage safe)
11) Nursing guidelines for patients undergoing Selectron treatments
12) Safety and backup systems
13) Emergency and error recovery procedures
14) Preventive maintenance recommendations and procedures.

NUCLETRON CORPORATION, 9008 Red Branch Road, Columbia, MD 21045 ■ Telephone: (301) 964-2249

Check List

Radiation Safety Testing of MicroSelectron

Patient: _____

Safety Test by: _____

Date: _____/_____/_____

1. After collecting the sources from the MicroSelectron LDR source container into the intermediate safe of the MicroSelectron, program the MicroSelectron for a test treatment using the auto radiographic test device.

2. Make an auto radiograph of all sources during the test treatment.

3. During the test treatment observe:

   a. All main console panel rights, remote console panel lights, and Nursing display console panel light function.

   b. Both primary and secondary timers on the main console and the remote console function (count) correctly.

   c. Treatment "ON" lights on the main, remote, and Nursing dispatcher console function properly.

   d. Radiation "ON" light on the independent radiation monitor function properly.

4. Observe that all sources retract into the safe, "OFF", at time "0", at all end of the elapsed test treatment time period, i.e., "safe" lights function on main and remote console, when the test treatment is finished.

5. Inspect the printout for proper listing of test conditions and time duration of test treatment.

6. Re-program the "test" treatment and initiate it a second time. Open the door and observe that;

   a. Sources retract into safe, i.e., Radiation "ON" light on the independent monitor is "OFF";

Check List

Radiation Safety Testing of MicroSelectron

b. Timer ceases counting;

c. Treatment "Interrupted" light functions on consoles and alarm sounds.

d. Observe that when the door is closed the sources remain in the safe, e.g. that the independent radiation monitor light stays "OFF".

ALARM CONDITIONS DURING TREATMENT

Computer-detected alarms during the use of the MicroSelectron fall into one (or more) of six categories, which are depicted both on the REMOTE CONTROL outside the room, and on the MICROSELECTRON CONSOLE inside the room. The NURSE STATION has only a non-specific ALARM light.

In all cases, an ALARM condition will be indicated by both audio (continuous "beep") and visual (red ALARM lights) signals. There is no audible indication inside the treatment room. The AUDIBLE OFF buttons will cancel the audio signal, but the ALARM lights will remain illuminated until the fault is rectified. The PRINTER on the MICROSELECTRON CONSOLE will show either an explicit error message, or an error code from which the malfunction can be determined. A list of these error codes follows this Section.

Below are brief descriptions of the Alarm Conditions. Procedures to be followed in the (unlikely) event of an alarm occurring are the responsibility of the individual hospital, and the radiation safety officer. Great care should be taken when drawing up a list of necessary actions.

SYSTEM: Indicates a computer or electronics-associated malfunction (extremely rare).

> **Warning:** *In the unlikely event that this indicator is alight, machine functions and displays may be suspect. Sources may be outside shielding. Treatment must be cancelled and the machine thoroughly inspected before putting it back in operation.*
>
> Note: *It is strongly recommended that the installation includes an independent gamma alarm to warn of sources outside the shielded safe.*

POWER: Indicates a loss of mains power to the MicroSelectron; either by loss of main hospital power, or by disconnection of the power cable while the unit is operational. Following a 30-second delay (to determine if power is speedily restored) the treatment is halted, the backup battery is being used to remove the sources from the patient applicator back into the lead radiation safe. The battery will also retain all treatment parameters in the computer memory for a period of up to 10 hours (dependent upon battery condition) for subsequent recall. A treatment print-out is initiated.

AIR: Indicates loss of air supply to the MicroSelectron; by loss of main hospital air, compressor malfunction (if fitted), or disconnection of air supply hose. In any event, treatment is halted and the sources returned to the radiation safe, and a treatment print-out initiated.

SOURCE: Indicates a source transit problem, either to or from the patient applicator or a fault in the source-array detection circuits.

Warning: A limited radiation hazard may exist inside room.

TIME: Indicates a computer timer error. The computer continuously monitors the difference between the primary and secondary timer circuits. In the event of the difference being outside preset limits, the treatment will be halted, and the sources returned to the radiation safe. A printout is given of the current treatment status and times.

LEAK: Indicates an air leak condition either in one of the applicators, or in the patient belt fitting (which joins the applicators to the umbilical hose).

Operator Responses to MicroSelectron Alarm Conditions

1. If the ALARM lights on the Nurses Display Console Lights, and the audible alarms sources, proceed to the door of the treatment room and identify on the remote control unit which alarm condition exists:

   a. Systems (computer or electronics) failure;

   b. Power loss;

   c. Air (pressure) loss;

   d. Source transit problem;

   e. Time (c lock) failure;

   f. Leak (air).

2. Consult the Response Chart and take the corrective actions indicated.

3. If the independent monitor radiation monitor light is "ON" while you are in the room attempting to restart the unit, the sources are not in the safe and a radiation field exists. Keep a maximum distance between your self and the patient; stand behind the lead shield while restoring function, if possible, and work efficiently to minimize your time in the room.

4. Resume treatment if the alarm condition is cleared; if not cleared, contact the radiotherapist or physicists, and minimize the time spent in the room if the independent radiation monitor is "ON".

RESPONSE CHART FOR MICROSELECTRON ALARMS

ALARM CONDITION	ARE SOURCES AUTOMATICALLY RETRACTED	SHOULD I ENTER ROOM AND PRESS "RESET" BUTTON	CORRECTIVE ACTIONS
System	No	No	Contact the Radiotherapist or Physicists immediately. Record elapsed times on the timers and record time of failure. Treatment can only resume after Physicists has corrected malfunction and reprogrammed device.
Power	Yes	Yes	Following a momentary or power loss of short duration use RESET button to restart unit after power is restored. Contact Radiotherapist or Physicist if unit fails to restart or if power loss is of longer duration.
Air	Yes	Yes	Use RESET button to restore functions; if RESET fails to remove alarm condition, contact the Radiotherapist or Physicists.
Source	No	Yes	Use RESET button. If alarm condition still exists, source is likely hung in source tube. Contact Radiotherapist or Physicists.
Time	Yes	No	If alarm occurs at the end of treatment session, notify Radiotherapist or Physicists; if alarm occurs during a session, immediately record time of occurrence and contact the Radiotherapist or Physicists.
Leak	Yes	Yes	Use RESET button; if alarm condition is not cleared enter the room and inspect all source guide tube connections. Patient may have attempted to disconnect source guide tubes. Call the Radiotherapist or Physicists if the alarm condition persists.