



October 18, 2004

U.S. Nuclear Regulatory Commission, Region III
Material Licensing Section
2443 Warrenville Road
Lisle, Illinois 60532-4352

RE: NRC License No. 21-01078-01

To Whom It May Concern:

Saint Mary's Mercy Medical Center has plans to move our Radiation Oncology department to a new location.

Please amend our NRC license as follows:

- 1) Add to our area of use the new Radiation Oncology Department, to be located on the lower level of the Lacks Cancer Center at Saint Mary's (see Appendix A). This building is connected to our main hospital but also has a separate entrance and therefore a separate address. The name and address is:

Lacks Cancer Center at Saint Mary's
250 Cherry Street, SE
Grand Rapids, MI 49503

Please include this address in our license so that radioactive shipments can be delivered directly to the radiation oncology department. The department includes three linear accelerator rooms and an isotope storage room. Our existing HDR unit will be stored and operated in linear accelerator room 3, labeled as A-vent-garde B.

A set of floor plans is included to show the relative location and distances of rooms containing radioactive material. Appendix B and C are drawn to the same scale and contain reference marks so that rooms above our HDR and isotope storage rooms can be identified. The floor-to-floor distance is 15 feet.

a) Isotope Room

- i) Room name will be Isotope Room (labeled on drawing, Appendix A).
- ii) All brachytherapy sources will be stored in a lead lined storage safe.
- iii) The isotope storage room will have lock-able doors. Keys will be available to the medical physicists, the dosimetrist and the radiation oncologists.
- iv) This room will be used to store the following sealed sources:
 - (1) I-125 seeds
 - (2) Cs-137 seeds
 - (3) Ir-192 replacement source for HDR unit.

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b) HDR Room

- i) All walls and ceiling in the HDR Brachytherapy room are 60 cm minimum thickness of Ledite with a density of 280 LB/cf. This room is on grade so shielding of the floor is not applicable. There are no windows and all conduits are underground or above the door in the shielded maze area.
- ii) Appendix D lists exposure rates and minimum shielding requirements for the HDR unit. For the purpose of these calculations we have assumed that all areas are unrestricted as defined in 10 CFR 20.1003, with an occupancy factor of 1.
- iii) Security and Safety
 - (1) A two-way intercommunication system will allow continuous communication with the patient during an HDR procedure. Two cameras for remote viewing, one with pan, tilt and zoom will allow continuous viewing of the patient on remote monitors during HDR procedures.
 - (2) If the intercommunication system fails then further HDR treatments will be suspended until replacement or repairs are completed. If both viewing cameras fail then further treatments will be suspended until replacement or repairs are completed.
 - (3) The HDR unit is stored in Linac Room Avant-garde B. The room is in the radiation oncology department. The doors to the department will be locked after office hours in accordance with 10 CFR 20.1801.
 - (4) An electrical interlock system is installed at the door to the treatment room. If anyone enters the maze during treatment the source will automatically retract into the HDR unit. Once the interlock is tripped further treatments will not be possible until the interlock is reset. If the interlock malfunctions the unit will be locked in the off position until repairs can be carried out and proper function is restored.
 - (5) A "CAUTION RADIOACTIVE MATERIAL" sign with minimum dimensions of 15 cm x 15 cm will be posted on the HDR room door.
 - (6) There is a linear accelerator unit and a superficial therapy unit in the HDR room. All three units will be connected to a switch allowing only the operation of one unit at a time.
 - (7) The keys to operate the HDR unit will be stored in the Medical Physicist's office.
 - (8) Periodic spot-checks will be performed in accordance with 10 CFR 35.643.

iv) Monitoring System

- (1) A permanent radiation monitor capable of continuously monitoring the source status is installed in the room. The monitor will give visible warning that the source is exposed, or partially exposed from the safe and will be observable by an individual entering the room.
- (2) The monitor is powered by a 110 volt connection and backed up by a rechargeable battery pack.
- (3) The radiation monitor will be checked by a dedicated check source each day before the HDR unit is used clinically. A record of these checks will be maintained for three years.
- (4) If the radiation monitor is found inoperable, any individual entering the room will be required to use a survey instrument to monitor any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source.

The survey instrument will be checked with a dedicated check source for proper operation at the beginning of each day of use.

- (5) The radiation monitor will be promptly repaired or replaced if found defective.
- v) A survey program will be implemented to demonstrate compliance with 10 CFR 20.1301 and 35.652. Surveys will be conducted following source exchange, service and when the device location changes from conditions in previous surveys.
 - (1) Maximum radiation levels at 10 cm from the nearest accessible surface surrounding the main source safe shall not exceed 1 mR/hr with the source in the shielded position.
 - (2) Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of limits specified in 10 CFR 20.1201.
 - (3) Radiation levels in unrestricted areas will not result in a dose to any member of the public in excess of the limits in 10 CFR 20.1301.
 - (4) Records of survey results will be maintained for inspection by the commission for the duration of the license.
- vi) Conspicuous, durable labels stating CAUTION RADIOACTIVE MATERIALS will be affixed to at least one outer surface of the device as specified in 10 CFR 20.1904.
- vii) Emergency Response
 - (1) We have developed and implemented written procedures for safe response to emergencies involving sealed sources in accordance with 10 CFR 20.1101 and 10 CFR 35.610 (if applicable).
- 2) Remove from our area of use the current Radiation Oncology Department including the Isotope Storage Room, which are all located on the first floor of our POB building (see Appendix E). Prior to release, all radioactive material will be removed and surveys will be conducted to demonstrate that ambient exposure rates and removable contamination are below the requirements for an unrestricted area. The results of this survey, including the survey instrument, the calibration date of the instrument, the person conducting the survey, and the survey results, will be forwarded to your office. This will all occur after we initiate service at the new Lacks Cancer Center site. We anticipate vacating the current Radiation Oncology Department in January, 2005. We will give your department the opportunity to inspect the current area prior to renovation and occupancy.
- 3) Please change the name on our license to: Saint Mary's Health Care. This change does not constitute a transfer of control of our license.

If additional clarification is required, please contact me at (616) 752-6744 or via e-mail at schipped@trinity-health.org

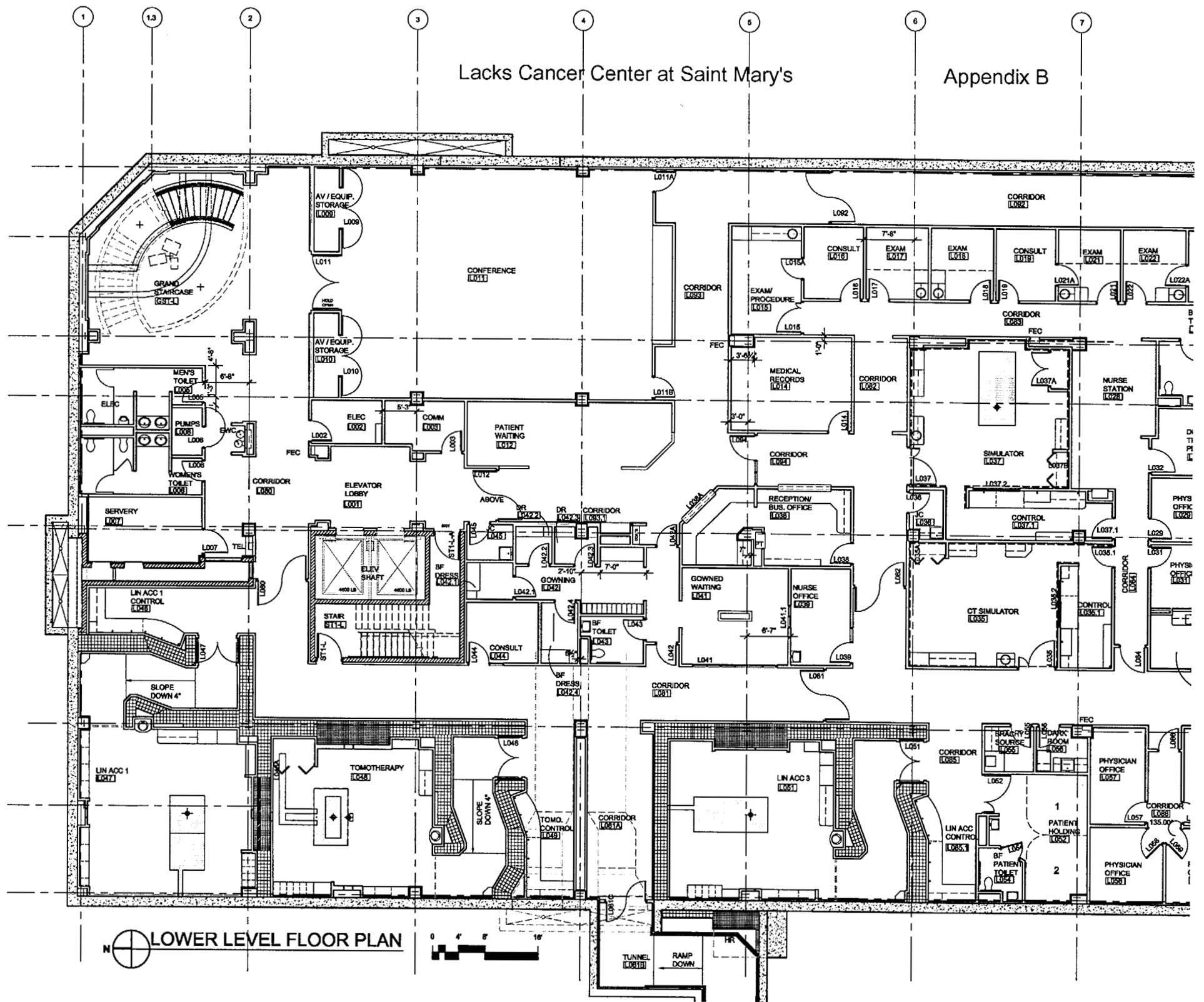
Sincerely,



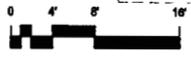
Dale J. Schippers, MS, DABR
Radiation Safety Officer



James Miller
Vice President and COO



LOWER LEVEL FLOOR PLAN



HDR Bunker Thickness and Design

Assumptions (NCRP #49)

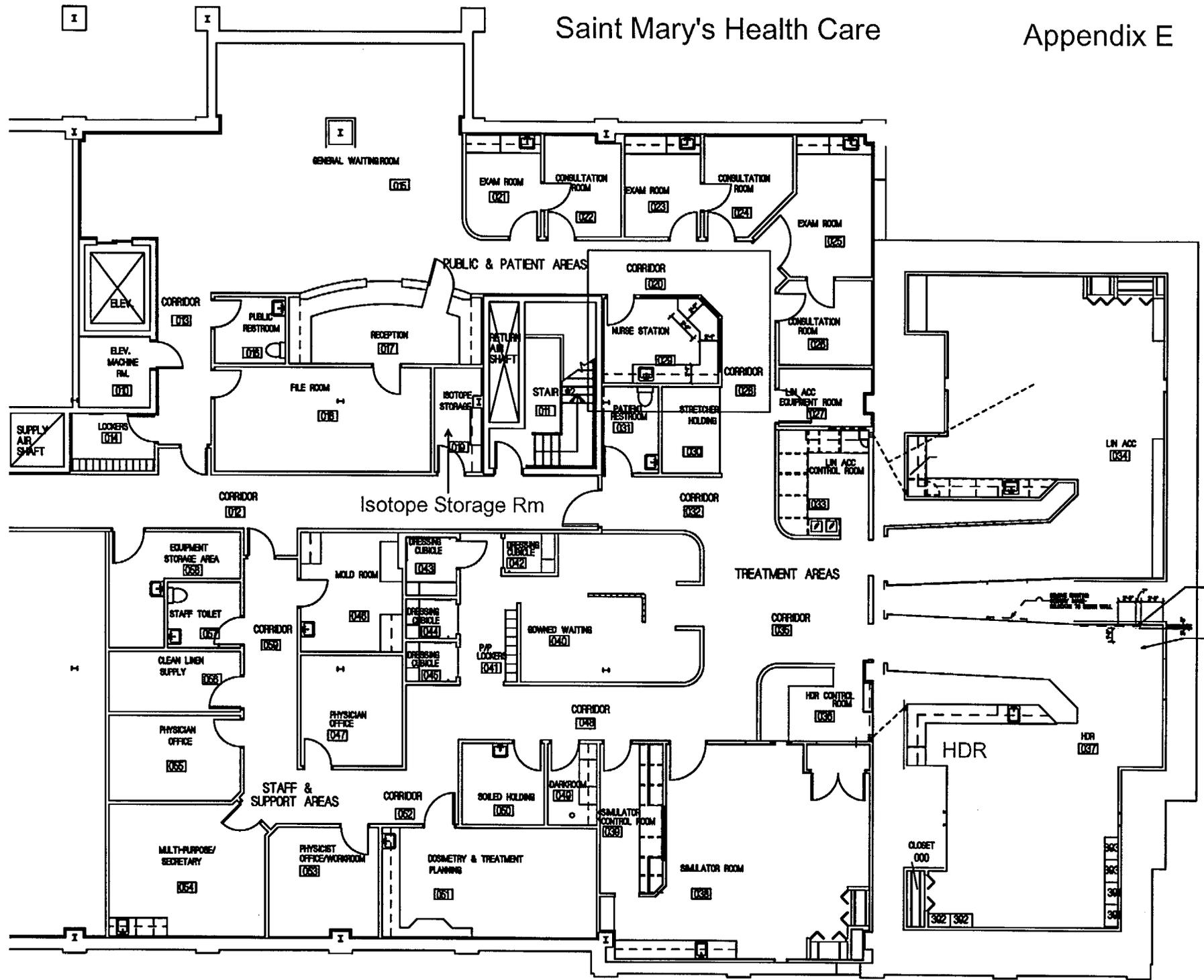
Exposure originates from closest point to an adjoining space
 exposure rate constant (ERC)= 0.5 R/h/Ci at 1 meter
 TVL for photons in concrete is 15 cm [NCRP 14.7 cm]
 All data is for standard concrete, density = 147 lb/cf
 Ledite density is 280 lb/cf
 Source activity = 10 Ci
 Attenuation by applicator and patient = none
 Closest individual is occupationally exposed
 Occupancy factor = 1 for all areas
 Use factor = 1
 Annual exposure limit is **100 mrem**
 Distance from source to area of interest.
 Inverse square factor calculated from source to area of interest.
 1 patient/day X 5 min/patient x 250 days/year = 21 hr/year
 Q.A.=29 hours/year (This is 5 times current workload)
 50 hr/year x 0.5 Rm²/Ci hr x 10 Ci

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Workload (W)

2.5 Gy/yr at 1 m

HDR ROOM									Required Thickness		
Distance	isf	W (Gy/y)	T	U	I (Gy/y)	*H (Gy/y)	I/H	TVL	Concrete cm	Lead cm	Ledite cm
1 m	1.000	2.5 Gy/yr	1	1	2.5000	0.0010 Gy/yr	2500.00	3.40	50.97	6.80	26.76
		4.2 mGy/hr			4.2 mGy/hr	0.02 mGy/hr	208.33	2.32	34.78	4.64	18.26
		416.7 mR/hr			416.7 mR/hr	2.0 mR/hr	208.33	2.32	34.78	4.64	18.26
2 m	0.250	2.5	1	1	0.6250	0.0010 Gy/yr	625.00	2.80	41.94	5.59	22.02
3 m	0.111	2.5	1	1	0.2778	0.0010 Gy/yr	277.78	2.44	36.66	4.89	19.24
4 m	0.063	2.5	1	1	0.1563	0.0010 Gy/yr	156.25	2.19	32.91	4.39	17.28
5 m	0.040	2.5	1	1	0.1000	0.0010 Gy/yr	100.00	2.00	30.00	4.00	15.75

The shielding is totally composed of Ledite which is no less than 60 cm at any point.



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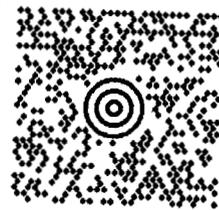
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1 LBS 1 OF 1

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