Amendment No. 77

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Harper Hospital	In accordance with letter dated May 5, 1992 3. License number: 21-04127-02 is amended in its entirety to read as follows:
2. 3990 John R. Street Detroit, MI 48201	4. Expiration date August 31, 1995
	5. Docket or Reference No. 030-02045

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. As needed
G. Uranium depleted in Uranium-235	G. Cadmium plated metal	G. As needed
H. Any byproduct material between Atomic Nos. 3 to 83, inclusive	H. Any nuclide, 6 curies total	H. 800 millicuries each

COPY

ML230102

I. Hydrogen-3	I. Any	I. 1 curie
J. Cesium-137	J. Sealed source (Technical Operations Model 72602)	J. No single source to to exceed 100 millicuries
K. Iridium-192	K. Sealed sources	K. No single source to exceed 10 curies 20 curies total
L. Americium-241	L. Any sealed or plated source approved by the NRC or Agreement State in accordance with 10 CFR 32.210	L. No single source to exceed 1 microcurie
M. Curium-244	M. Any sealed or plated source approved by the NRC or Agreement State in accordance with 10 CFR 32.210	M. No single source to exceed 5 microcuries
N. Cesium-137	N. Any sealed source approved by the NRC or Agreement State in accordance with 10 CFR 32.210	N. No single source to exceed 200 millicuries
O. Carbon-14	O. Solid and/or liquid waste	O. See Item 9.O. below
P. Hydrogen-3	P. Solid and/or liquid waste	P. See Item 9.P. below
Q. Sulfur-35	Q. Solid and/or liquid waste	Q. See Item 9.Q. below

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 21-04127-02

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9. (Continued)

D. Medical use described in 10 CFR 35.400.

E. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

F. In vitro studies.

G. Shielding in a linear accelerator.

H. and I. To be used in medical research, diagnosis and therapy as defined in 10 CFR 30.4.

J. To be used for instrument calibration.

K. To be used in Nucleotron Corp. Micro-Selectron - HDR remote afterloading device for interstitial and intercavitary treatment of cancer. One source set to be held in its shipping container incident to source exchange.

L. through N. To be used for instrument calibration.

O. through Q. Possession incident to interim storage of waste in accordance with statements, representations, and procedures contained in letter dated May 5, 1992.

CONDITIONS

10. Location of Use: 3990 John R Street, Detroit, Michigan, and 18700 Meyers Road, troit, Michigan.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Jaroslaw Muz, M.D., Chairman.

B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

C. The Radiation Protection Officer for the activities authorized by this license is Lawrence Davis, M.D. The Assistant Radiation Protection Officer for medical research as defined in 10 CFR 30.4 is Thomas Kumpuris.

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicting that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than Hydrogen-3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months; except those sealed sources as specified by the manufacturer and specifically authorized by the Commission or an Agreement State may be leak tested at intervals not to exceed three years. Each source designed for the purpose of emiting alpha particles shall be tested at intervals not to exceed 3 months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action taken.

13. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

15. Experimental animals administered licensed materials or their products shall not be used for human consumption.

16. Training of staff in use of licensed material specified in Subitem K. shall be conducted by Nucletron Corporation personnel authorized by State of Maryland License No. MD-27-035-01 to conduct such training.

17. A. Access to the room housing the MicroSelection-HDR irradiation device shall be controlled by a door at each entrance.

    B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off control is reset at the control panel.

    C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

    D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

18. Prior to initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron-HDR, radiation surveys and tests shall be performed in accordance with the following:

    A. A radiation survey shall be made of:

        (i) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the source head shall not exceed 0.25 milliroentgens per hour.

        (ii) All areas adjacent to the treatment room with the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

            (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation" (10 CFR 20).

18. (Continued)

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b) 10 CFR 20.

B. Records of the survey results shall be maintained for inspection by the Commission.

19. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of sources contained in the Selectron-HDR and MicroSelection-HDR irradiation devices.

B. Any maintenance or repair operations on the irradiators involving work on the source head, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

20. Human - use research and development shall be conducted in accordance with protocols approved by the Harper Hospitals Radioactive Drug Research Committee (RDRC No. 0141).

21. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

22. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35 (J) for establishing decommissioning financial assurance.

23. The licensee shall maintain records of information important to safe and effective decommissioning at 3990 John R Street, Detroit, Michigan per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 21-04127-02

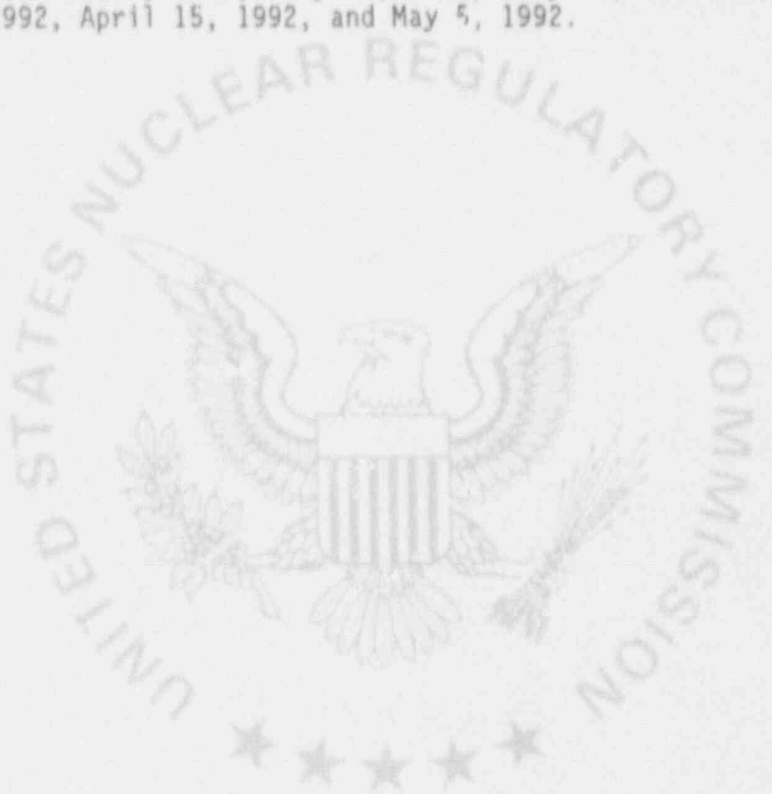
Docket or Reference number 030-02045

Amendment No. 77

24. This license is based on the licensee's statements and representations listed below:

A. Application dated February 8, 1990.

B. Letters dated June 7, 1990, July 23, 1990, July 16, 1991, October 4, 1991, April 10, 1992, April 15, 1992, and May 5, 1992.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date August 26, 1992

By George F. McCann
Materials Licensing Section, Region III

COPY

JUN 12 1992

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B
EXP. DATE: 19950831
FEE COMMENTS: CODE 23
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION III

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: HARPER HOSPITAL
   RECEIVED DATE: 920528
   DOCKET NO: 3002045
   CONTROL NO.: 393537
   LICENSE NO.: 21-04127-02
   ACTION TYPE: AMENDMENT

2. FEE ATTACHED
   AMOUNT: 0
   CHECK NO.:

3. COMMENTS
   Add'l info to CN 90885 per [illegible]

SIGNED R. [illegible]
DATE 6-3-92

FEE NOT REQUIRED

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓)

1. FEE CATEGORY AND AMOUNT: 7B Add'l Info 390885

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ✓
   RENEWAL
   LICENSE

3. OTHER

SIGNED Rita Jacques
DATE 6/9/92

7

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

AUG 26 1992

TO THE LICENSEE:

Enclosed is the NRC license or license amendment which you requested.

You are encouraged to carefully review your license or amendment upon receipt as special conditions may have been added to ensure that the changes requested meet NRC requirements.

Any future correspondence relating to your license should specifically reference your license number to expedite your inquiry.

Should you have any questions regarding your new license or amendment or require clarification, please contact the Materials Licensing Section at (708) 790-5625.

Materials Licensing Section

Enclosures: As stated

HARPER HOSPITAL
RADIATION SAFETY COMMITTEE

May 5, 1992

U.S. Nuclear Regulatory Commission
Material's Licensing Section
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: Control Number 90885

Dear Sirs:

The following information is submitted in response to a request for additional information under control number 90885 for Material's License 21-04127-02. The extensive delay in our response has been caused by unforeasted delays in gathering the required information, ie. close-out surveys for spaoe recently vacated.

Radiation Safety Officer

Additional information regarding this issue in particular has been previously forwarded to the Material's Licensing Section under this control number dated 4/10/92 and control number 93294 dated 4/15/92.

Location of Use

Enclosed please find the close-out surveys for the areas of approved use of radioactive material at 18700 Meyer's Road, Detroit, Michigan. We have noted as requested the following information:

a. A diagram of the areas keyed with survey and wipe test results.
b. The name of the person performing the surveys.
c. The date each survey was performed.
d. The instruments used in the analysis of wipes plus the survey meter used at this time of the survey.
e. The background readings.
f. The dates that the survey instruments were calibrated when used.

FEE NOT REQUIRED
addl info 390885

If these data are acceptable, please remove 18700 Meyer's Road, Detroit, Michigan as a location of use.

Interim Storage of Low Level Waste

Please find enclosed our responses to "Attachment 1 of Information Notice No. 90-09" to support our request for extended interim storage of low-level radioactive waste.

If you have any questions about the information submitted or require additional information please contact us.

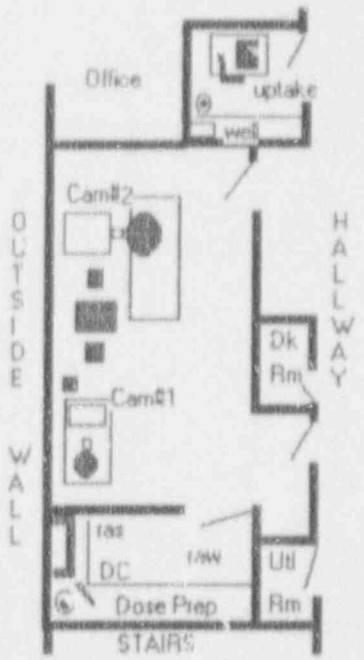
Sincerely,

Shirley L. Green

Shirley L. Green
Vice President, Patient Services

GRACE HOSPITAL
DIVISION OF NUCLEAR MEDICINE
18700 Meyers Road
Detroit, Michigan

CLOSEOUT SURVEY - 3/29/91
21-04127-02



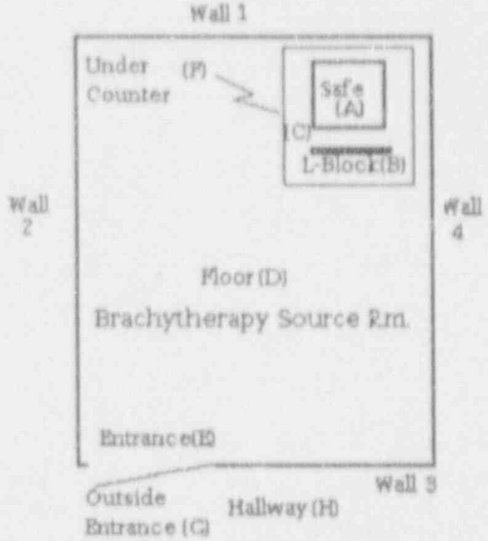
Data noted below was collected by Michele Marshall, R.T., Chief Nuclear Medicine Technologist on a Canberra NaI(Tl) Well Counter/MCA and Bicron Side Window GM meter calibrated on 5/1/90.

AREA	WIPE TEST dpm	AREA SURVEY mR/hr
Background	890	0.02
Dose Prep	815	0.02
Radioactive Waste (raw)	830	0.02
Dose Calibrator (DC)	785	0.02
Radioactive Storage (ras)	840	0.02
Hot Lab Floor	810	0.02
Camera #1	850	0.02
Camera #2	810	0.02
Hallway	855	0.02
Uptake	870	0.02

CONTROL NO. 93537

GRACE HOSPITAL
DIVISION OF RADIATION ONCOLOGY
18700 Meyers Road
Detroit, Michigan

CLOSEOUT SURVEY - 2/20/92
21-04127-02



Data noted below was collected by Farideh R. Bagne, Ph.D., J.D., Chief Physicist, Radiation Oncology on a Canberra NaI(Tl) Well Counter/MCA and Bicron Side Window GM meter calibrated on 5/22/91.

AREA	WIPE TEST Gross dpm	AREA SURVEY mR/hr
Background	622	0.02
A. Safe	620	0.02
B. L-Block	620	0.02
C. Front of Counter	622	0.02
D. Floor	619	0.02
E. Entrance	622	0.02
F. Under Counter	621	0.02
G. Outside Entrance	620	0.02
H. Hallway	615	0.02
Wall 1, 2, 3, 4	N/A	0.02

AMENDMENT REQUEST TO AUTHORIZE

EXTENDED INTERIM STORAGE OF LOW-LEVEL RADIOACTIVE WASTE

1. Identification of Waste to be Stored

a. Specify any possession limit increases needed for extended interim storage of low-level radioactive waste.

Our current NRC license states the following possession limits:

H-3 1 Curie

Any Byproduct Material between Atomic numbers 3 to 83 inclusive
800 mCi each, or 6 Curies total

These possession limits should be adequate for the storage of low-level radioactive waste. If the need arises to increase these limits we will apply for an amendment. We are currently well below these limits.

b. Identify the estimated maximum amount of low-level Radioactive waste to be stored, both in terms of volume and activity, by radionuclide.

C-14:
Activity: We currently have no research activities which involve the use of C-14. We do however have one researcher who is authorized for the use of C-14.

Total activity used over the last two years.

1990-91: 0.0 mCi
1991-92 0.0 mCi

Estimate of yearly accumulation: < 100 uCi

Physical Form: Dry Solid Waste

Generated Volume: < 1 cubic feet

H-3: Most of our low-level radioactive waste for long term storage is H-3. We currently have 4 researchers who are authorized for use of H-3. Typically, 75% of their waste (activity) is in the form of an aqueous based liquid. This is counted in a liquid scintillation counter and disposed of via the sewer system in accordance with 10 CFR part 20. Another 15% of the waste would be in the form of solid waste. The remaining 10% would be deregulated concentrations in the form of scintillation vials. We use only aqueous based scintillation fluids at this institution. These are in concentrations which are deregulated by the NRC. These are in the process of being shipped via a licensed hazardous waste vendor (ADCO) to a disposal site. We will not generate any mixed (hazardous/radioactive) waste in the future.

Total activity used over the last two years.

1990-91: 0.0 mCi
1991-92 5.2388 mCi

Estimate of yearly accumulation: < 50 mCi

Physical Form: Dry Solid Waste

Generated Volume: < 27 cubic feet

S-35: We currently have four researchers who are authorized to use S-35 and do not anticipate any more in the future. All research activities that pertain to S-35 have been discontinued, therefore we expect our use to decrease to even lower levels. The bulk of this will be disposed of as aqueous liquid via the sewer system in accordance with 10 CFR part 20.

Total activity used over the last two years.

1990-91: 2.3309 mCi
1991-92 0.4019 mCi

Estimate of yearly accumulation: < 100 uCi

Physical Form: Dry Solid Waste

Generated Volume: < 1 cubic foot

c. Characterize the low-level radioactive waste to be stored:

(1) Volume of waste by Class (A, B or C)

All waste generated will be class A.

(2) Physical form of the waste: solid, liquid or gas.

All of the waste stored will be in the solid form. These solids include contaminated plastic, glass, paper and other solids. There will be no bio-hazards associated with this waste. All liquid waste generated is typically an aqueous based solution. At this point in time all liquid waste now generated is disposed of via the sewer system. This is done in accordance with 10 CFR 20. There will be no generation of liquid waste for extended storage. All scintillation vials that are generated are in concentrations that are exempt from NRC regulations. These vials contain only aqueous based scintillation fluid and are not considered a hazardous waste. These are shipped out to a licensed hazardous waste vendor only as a matter of convenience.

(3) Waste Processing: Volume Reduction, solidification or other treatment.

At this point in time there is no need for any of the above methods. If the need does arise we will request an amendment for the use of a compactor.

(4) Additional non-radioactive properties of low-level radioactive waste: (hazardous, biologic/pathologic, corrosive, flammable ect.

Hazardous Waste: At this point in time we are not generating any waste that could be considered hazardous such as organic based scintillation fluids. If any are generated they would be most likely be in small amounts and in concentrations that would be exempt from NRC regulations. These would then be disposed of via a licensed hazardous waste vendor. We are currently in possession of some hazardous waste. These containers are in the form of four 55 gallon drums of organic based fluids. We are now in the process of determining the actual concentrations of these barrels. If these are in concentrations that are considered deregulated they will be shipped off-site to an approved disposal site via an hazardous waste vendor.

Biologic/Pathologic: All associated bio-hazards with any research activities will be handled in the following way. All contaminated wasted will be treated with a virucidal agent (bleach). All waste will then be autoclaved prior to it's disposal as radioactive waste. We will not store or generate any mixed waste.

Corrosive: None of the stored material will be corrosive.

Flammable: Any flammable material will be in the form of organic based scintillation fluids. These will be disposed of via a hazardous waste vendor. Any storage would only be short term and is not anticipated.

d. Describe the amount and type of low-level waste being stored or processed.

We are currently in the possession of anproximately 36 cubic feet (6 -55 gallon drums) of dry solid waste (H-3 and C-14). This solid waste is being held for decay-in-storage. In addition to the solid waste we are in possession of (2- 15 gallon barrels) of aqueous based liquid waste. This waste is being processed for disposal via the sewer system. All other waste on site is being held for decay-in-storage.

e. Identify any additional permits or approvals necessary for storage (i.e., EPA hazardous waste permit, State or local approvals, etc.)

Not Applicable: The State of Michigan does not have storage permit requirements for low-level radioactive waste. The Department of Natural Resources (DNR) controls mixed waste (radioactive and hazardous). The hospital generates below exempt quantities making it exempt from the State of Michigan Hazardous Waste Management Public Act 64.

2. Plans for Final Disposal:

a. Specify when disposal capacity will no longer be available to you and on-site storage will begin.

Hospitals in Michigan generating low-level radioactive waste are currently denied access to the three sited regional compacts around the country. Any solid low-level radioactive waste (T1/2 > 65 days) has been stored at this institution since denial of access to the waste sites. As you know there is currently a number of appeals on the recent rulings by the Federal court system.

b. Specify the State/Regional disposal facility to be used for the ultimate disposal of your low-level radioactive waste and when that facility is scheduled to begin accepting low-level radioactive waste.

Hospitals in Michigan generating low-level radioactive waste are actively pursuing an answer to the disposal and/or interim storage problem. No concrete answer to the location of the final disposal site can be given at this time.

c. Specify when you will begin shipping low-level radioactive waste to that facility and how long it will take for your estimated storage inventory to be moved out.

As stated in item 2.b a site for the permanent disposal does not exist. When a site for final disposal has been determined, all waste will be shipped in accordance with NRC, State, DOT and local regulations. Once a site does become available, all waste will be shipped off-site within 3 months.

3. Physical Description of Storage Area

a. Identify the location and provide a diagram of the low-level radioactive waste storage area which demonstrates where packages will be stored and how packages will be accessible for inspection purposes. Include the locations of waste processing equipment (if applicable), air sampling stations, effluent filters and any sources of flammable or explosive material.

The location of the waste is in the Harper Webber Building. The storage room is located above the morgue in a sub-basement of the main hospital and is accessible only via a key operated elevator and/or a five foot elevator to a secured stairway. The storage area is in an underground concrete room. The walls, floor and ceiling are all made of 18" thick concrete. The area comprises 475 square feet.

The area is properly posted according to 10 CFR part 19. All waste will be stored in metal drums with sufficient spacing to inspect them. Barrels may be double stacked in order to increase available storage. (See Enclosed Diagram)

b. Specify the maximum volume of low-level waste that can be stored in the proposed waste storage area and relate this to the annual volume of waste generated.

The waste storage area holds approximately (50) 55 gallon drums. We are currently in possession of (4) 55 gallon drums of solid waste and (2) 15 gallon drums with a half-life of >65 days. We expect to generate approximately 2 to 3 barrels per year of low-level radioactive waste with a half-live of greater than 65 days. This would generate 15 barrels over a 5 year period and approximately 30 barrels over a ten year period. The yearly generation of solid waste will constitute less than 10% of the total available storage area. This is assuming no increase in the generation of waste. We are however not expecting such an increase in the future. Our experience in the past two years has shown a definite decrease in the amount of waste generated by the research areas. We are constantly encouraging researchers to find new techniques which do not require the use of radioactivity. If the storage area starts to approach capacity, we would most likely use some method of compacting waste.

c. Specify the type of building/structure in which the waste will be stored and demonstrate that the waste will be protected from the weather at all times.

The storage area is in an underground concrete room. The walls, floor and ceiling are all made of 18" thick concrete. The room is heated to ambient room temperature via heating vents. Waste has been stored in this room for the previous 15 years with no evidence of damage to the facility or waste due to weather conditions.

d. Describe the measures to control access to the low-level waste storage area and thereby ensure security of the waste.

Access to the storage area is by elevator and/or access door. Both require the use of lock and key. The personnel having access to this area are the consulting physicists, Radiation Safety Officer and Security personnel. Security personnel receive yearly in services as to the hazards associated with ionizing radiation and to whom access shall be granted.

e. Describe the ventilation system and how it will assure adequate ventilation of the storage area.

Exhaust air is vented via an exhaust fan with an approximate air-flow of 100 cfm.

f. Describe the fire protection and suppression system to minimize the likelihood and extent of fire.

No fire suppression or detection system is located in the room. The room is enclosed by concrete walls, ceiling and floor. These concrete barriers provide a minimum of 4 hour fire barriers.

g. Describe how the adverse effects of the extremes of temperature and humidity on waste and waste containers will be avoided.

The area is heated and does not have a large variation of temperatures. The exhaust fan will keep the effects of humidity to a minimum. The containers will be checked quarterly for these adverse effects.

h. Describe the vulnerability to other hazards such as tornado, hurricane, flood, or industrial accident, ect.

The room location (underground) does not make it vulnerable to drastic weather conditions such as tornadoes. The area does not have any running water in the area and therefore the likelihood of a flood is also remote. All waste is however stored in sealed 55 gallon drums which would maintain their integrity in this case. The likelihood of an industrial accident in this area is also remote.

4. Package and Container Integrity

a. Describe the package or containers to be used for storage of low-level radioactive waste, any hazards the waste may pose to their integrity, and the projected storage life of the packages or containers.

The 55 gallon drums used for disposal are DOT approved and tested. These drums are typically supplied by ADCO for this purpose. The projected life of these barrels in the conditions described above is greater than 50 years. Prior to the waste being stored in these barrels a layer a absorbent is applied to the bottom. The barrel is then lined with two 6 mil plastic bags. The bags are the tied and sealed for storage. Sharp objects contaminated with long-lived radioactive material will be separated and stored in thick plastic containers (e.g. syringe containers) to avoid the risk of puncturing plastic bags. The estimated storage life of a full container is greater than 50 years.

b. Describe your program of periodic inspections of low-level radioactive waste packages to ensure that they retain their integrity and containment of low-level radioactive waste.

The waste area is inspected at least monthly by the consulting medical physicist. This shall include a visual inspection of all containers for any loss of integrity or damage. The area will also surveyed and wipe tested for removable contamination by personnel from the Nuclear Medicine staff at least monthly

Wipe testing for removable contamination will also include a random selection of the 55 gallon drums. The wipe test results will be recorded in dpm's. These surveys and wipe tests will be documented and reviewed by the radiation safety officer.

c. Describe your program and equipment (if applicable) for remote handling and/or repackaging damaged or leaking waste containers.

The waste generated will be only low energy beta emitters. Therefore no remote handling tools will needed or used. If a barrel is found to be leaking we will initiate the Emergency Procedure for a Radioactive Spill found in our NRC license application. After we have disposed of the two (2) 15 gallon drums, No liquid waste will be stored so contamination due to leakage is negligible. If however a leaking barrel is found we have in possession absorbent and the normal safety equipment e.g. (emergency spill kits, survey meter, blue pads, lab coats, rubber gloves, liquid scintillation counter, decontaminate, and siphon for the removal of the liquid to another barrel. Normal safety precautions will be used whenever handling radioactive waste.

5. Radiation Protection

a. Describe your program for safe placement and inspection of waste in storage and maintaining occupational exposures as low as is reasonably achievable (ALARA). This program should include periodic radiation and contamination surveys of individual packages and the storage area in general, as well as posting the storage area in accordance with 10 CFR 20.203.

i. Logs will be kept of the amount of liquid low-level radioactive waste placed into the sanitary sewer system, solid waste placed in designated containers and of exempt quantities in aqueous based scintillation vials disposed of via a hazardous waste vendor. The aqueous based scintillation fluid does not require it to be disposed of this way, but we will do so as a matter of convenience.

ii. Containers for solid low-level radioactive waste are made of steel and approved by the DOT. A layer of absorbent will be placed in the bottom of the drum for possible leakage. An inner liner of two (6 mil) thick plastic bags will be placed in the containers.

iii. The radiation safety officer or his designee will inspect the logs for proper recording of disposal and transfer of the waste to the storage area on a quarterly basis.

iv. The waste will be double-bagged and properly labeled with the isotope, date, and the amount of activity and initials of the person disposing of the waste.

v. A thin end-window GM meter will be used for surveying the low-level radioactive waste. Exposures rates will be recorded in the appropriate log and reviewed the radiation safety officer. These surveys will be done at least monthly.

vi. Surveys for removable contamination will done monthly. These will be performed using a liquid scintillation counter. All values will be recorded in dpm's. These values will be recorded in the appropriate log and reviewed by the radiation safety officer or their delegate. Random wipe test of waste containers will also be monthly.

vii. The door access to the waste storage area will be posted in accordance 10 CFR part 20. All other required postings both State and Federal will also be displayed prominently.

viii. All personnel will be supplied with the appropriate personal monitoring device. The results will be reviewed by the consulting physicist and/or the radiation safety officer.

b. Describe the projected exposure rates, needs for shielding (if any) and any changes in personnel monitoring which will be required as a result of waste storage.

Due to the characteristics of the stored byproduct materials (Beta emitters) and the amount of stored activity the exposure rates will be at or slightly above background. There will be no expected changes in the current exposure monitoring of personnel.

c. Describe your procedure for responding to emergencies, including notification of and coordination with local fire, police and medical department.

In the case of emergencies, hospital security would be notified. Security has the appropriate telephone numbers for both the radiation safety officer's office and home. Security personnel has been instructed as to the correct method of handling emergencies concerning restricted areas. These numbers are posted on the entrance to the storage area.

d. Describe your system for maintaining accurate records of waste in storage (including any waste receipts or transfers from or to other licensees) to assure accountability.

All waste that is deposited in the waste containers by the researchers will be logged in with the following information: Name of Researcher, Isotope, Estimated Activity, Physical Form, Date and Initials. Once the barrel has been filled, the total activity will be logged on the form and initialed with the date. This form is then affixed to the barrel. This form will then stay with the waste until the time of final disposal. When the waste is transferred to a site for disposal all the appropriate shipping and transfer records will be saved. A quarterly total (inventory) of all waste stored will be tallied to ensure we are within the possession limits. These values will then be reported at the quarterly Radiation Safety meeting.

6. Training

a. Describe your program for training personnel in procedures for packaging, handling, placement, inspection, surveying and emergency response for low-level radioactive waste storage.

Training for laboratory personnel using byproduct materials at Harper Hospital includes the review of all pertinent procedures with the consulting physicist:: :
Rules for Safe Use of Radioactivity
Rules for Ordering and Receiving Radioactive Materials
Rules for the Disposal of Low-Level Radioactive Waste
Hazards Associated with Ionizing Radiation
Emergency Procedures for Handling Radioactive Spills
Safety Factors for Laboratory Personnel

Training for Security personnel will include the following:
Hazards Associated with Ionizing Radiation
Emergency Procedures for Handling Radioactive Spills and/or Emergencies

These will be done yearly and at the time of employment

7. Financial Assurance

a. Review the relevant sections of Parts 30, 40 and 70 regarding financial decommissioning. If your proposed maximum possession limits exceed the limits specified in Sections 30.35, 40.36, or 70.25, submit with your amendment request a decommissioning funding plan or certification of financial assurance, as appropriate. In either case, this submittal should demonstrate that are or will be in place not only to decommission the licensed operation, but also to provide for the estimated costs of handling, transport and ultimate disposal of all low-level radioactive waste on site.

We will keep the quantities stored on-site below our current maximum possession limits. We are therefore below the limits which require Financial Assurance for decommissioning. Should we approach these limits we will file the requested information at that point in time.

8. Emergency Preparedness:

a. Review the relevant sections of Parts 30, 40 and 70 regarding Emergency Preparedness. If your proposed maximum possession limits exceed the limits specified in subsections 30.22 (i) (1), 40.31 (j) (1) or 70.22 (i) (3), you will be required to either demonstrate that an emergency plan is not needed or to develop and maintain a plan that meets the requirements of the aforementioned sections.

Not Applicable

LOW LEVEL RADIOACTIVE WASTE STORAGE ROOM HARPER HOSPTIAL