

## MATERIALS LICENSE

Amendment No. 82

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or 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.

301987

Licensee		In accordance with letter dated October 8, 1996 3. License Number 21-04127-02 is amended in its entirety to read as follows:	
1. Harper Hospital			
2. 3990 John R. Street Detroit, MI 48201		4. Expiration Date August 31, 2000	
		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. Carbon-14	H. Any	H. 25 millicuries	
I. Phosphorus-32	I. Any	I. 100 millicuries	
J. Phosphorus-33	J. Any	J. 100 millicuries	
K. Sulfur-35	K. Any	K. 50 millicuries	

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

21-04127-02

Docket or Reference Number

030-02045

Amendment No. 82

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|---|--|--|
| 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 |
| L. Scandium-46  | L. Any   | L. 25 millicuries  |
| M. Chromium-51  | M. Any   | M. 50 millicuries  |
| N. Hydrogen-3   | N. Any   | N. 1 curie   |
| O. Cesium-137   | O. Sealed source (Technical Operations Model 72602)  | O. No single source to exceed 100 millicuries                                  |
| P. Iridium-192  | P. Sealed sources  | P. 1 source not to exceed 12 curies, and 1 source not to exceed 10 Ci.         |
| Q. Americium-241                                      | Q. Any sealed or plated source approved by the NRC or Agreement State in accordance with 10 CFR 32.210 | Q. No single source to exceed 1 microcurie                                     |
| R. Curium-244   | R. Any sealed or plated source approved by the NRC or Agreement State in accordance with 10 CFR 32.210 | R. No single source to exceed 5 microcuries                                    |
| S. Cesium-137   | S. Any sealed source approved by the NRC or Agreement State in accordance with 10 CFR 32.210           | S. No single source to exceed 200 millicuries                                  |
| T. Carbon-14  | T. Solid and/or liquid waste   | T. See Item 9.0. below   |
| U. Hydrogen-3   | U. Solid and/or liquid waste   | U. See Item 2 P. below   |

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|---|--|--|
| 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 |
| V. Sulfur-35  | V. Solid and/or liquid waste                           | V. See Item 9.Q. below   |
| W. Californium-252                                    | W. Sealed sources (U.S. Department of Energy Model AT) | W. No single source to exceed 33 micrograms, 1 milligram total                 |

## 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.
- 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. through N. To be used in laboratory research and development as defined in 10 CFR 10 CFR 30.4, including animal studies.
- O. To be used for instrument calibration.
- P. One source to be used in a Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 10 Curies at the time of installation. One source in its shipping container for source replacement.
- Q. through S. To be used for instrument calibration.

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

W. To be used for interstitial and intracavitary treatment of cancer as described in Letter dated March 3, 1993.

CONDITIONS

10. Location of Use: 3990 John R Street, Detroit, Michigan.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Arthur Bradley Eisenbrey, M.D., Ph.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 transferor indicating 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 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 emitting 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.

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- C. 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.
- D. 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, 801 Warrenville Road, Lisle, Illinois 60532-4351, 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.

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- 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).
    - (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. 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.

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21. 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 (d) for establishing decommissioning financial assurance.
22. 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.
23. 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, May 5, 1992, March 3, 1993, January 4, 1994, July 19, 1994 (excluding in-house training program), and October 8, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

Nov 15, 1996

By

Edlyn R. Moten

Nuclear Materials Licensing Branch, Region III

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BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 02230  
Status Code: 0  
Fee Category: 7C 2B  
Exp. Date: 20000831  
Fee Comments: 7C EFF 10/21/93  
Decon Fin Assur Req'd: N

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: HARPER HOSPITAL  
Received Date: 961028  
Docket No: 3002045  
Control No.: 301987  
License No.: 21-04127-02  
Action Type: Amendment

2. FEE ATTACHED

Amount: 440  
Check No.: 458938

3. COMMENTS

Signed D. Hensley  
Date 11-27-96

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

1. Fee Category and Amount: 7C 2B \$440

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

Amendment ☒  
Renewal ☐  
License ☐

3. OTHER

Signed SC  
Date 11/4/96

NOV 07 1996

Log	Nov 2 III
Remitter	
Check No.	458938
Amount	440
Fee Category	7C 2B
Type of Fee	Amend
Date Check Rec'd	11/4/96
Date Completed	11/4/96
By:	SC

1996 NOV -4 AM 9:23

Wayne State University

**DMC**

**Harper  
Hospital**

October 8, 1996

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Branch  
801 Warrenville Road  
Lisle, Illinois 60532-4351

Re: Amendment to 21-04127-02

Dear Sirs:

We wish to amend our Material's License 21-04127-02 concerning the source possession limits for our Microselectron-HDR. This amendment for increased source activity shipments, is made necessary by a new Special Form Certification that Nucletron has received.

<u>Byproduct Material</u>	<u>Chem. &amp; Phys. Form</u>	<u>Max. Possession Activity Limit</u>	<u>Purpose</u>
Iridium-192	Sealed Sources	No single source to exceed 12 Ci, 24 Ci total	Nucletron Microselectron HDR

We confirm that no source greater than 10 Ci will be installed by a Nucletron engineer in a remote afterloader. Supporting documentation regarding this issue from Nucletron Corporation is enclosed for your review.

We look forward to our amendment as soon as possible. We have enclosed our hospital check for \$440.00, payable to the US Nuclear Regulatory Commission as required. If you have any questions please contact us.

Sincerely,

*Shirley L. Green*

Shirley L. Green  
Vice President  
Patient Services

Harper Hospital  
3990 John R Detroit, Michigan 48201 313.745.8040

*Pm: 10-23-96*

**RECEIVED**

**OCT 28 1996**

**REGION III**

*301987*

**OCT 28 1996**



**nucletron®**

NUCLETRON CORPORATION

7080 Columbia Gateway Drive  
Columbia, Maryland 21046-2133

Telephone: 410-312-4100  
FAX: 410-312-4199

January 20, 1995

Attn: All Radiation Safety Officers

**RE: LICENSE AMENDMENT - MICROSELECTRON-HDR SOURCE POSSESSION LIMITS**

Dear Radiation Safety Officer:

Nucletron has recently received Special Form Certification for the microSelectron-HDR source manufactured by Mallinckrodt Diagnostica in Holland. As a result of this certification, it is possible to ship microSelectron-HDR sources to customers with greater than 10Ci activity on the date of shipment.

Most licensees are limited to possession limits of 10Ci per source for the two sources listed on the license. To enhance the ability of each licensee to have a 10Ci source installed in their remote afterloader on schedule, Nucletron wishes to ship the sources at approximately 11.5Ci to each customer prior to the source exchange.

Each licensee must amend their Radioactive Materials License to authorize a possession limit of 12Ci per source with the stipulation that no source greater than 10Ci will be installed by a Nucletron engineer in a remote afterloader. The documents accompanying the source will indicate the Special Form Certification.

After the amendment has been received by the licensee, please fax a copy to Nucletron Corporation at 410-312-4197.

Should you have any questions concerning this letter, please contact the undersigned directly.

Sincerely,

NUCLETRON CORPORATION

Stephen P. Teague

Technical Manager/Radiation Safety Officer

Federal Agency for Research and Testing of Materials  
(BAM)

License

for the design of a  
"special form radioactive material"  
D/0046/S (Rev. 2)

1. Applicant and Holder of License:

Nucletron Holding B.V., NL-3900 AX-Veenendaal

2. Decisive Regulations:

This license is issued in accordance with the requirements for "special form radioactive material" of the IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 Edition (Supplement 1990) and with the corresponding national and international regulations such as

- the ordinance regarding national and international highway transport of hazardous commodities (Ordinance Regarding Hazardous Commodities on Highways, abbr. GGVS) of July 22, 1985, amended by the 3. amendment to the Ordinance Regarding Hazardous Commodities, Highways of June 18, 1990 (BGBl. I p. 1325), Appendix A, Margin number 3731.
- European Agreement on International Highway Transport of Hazardous Commodities (ADR-Agreement) of September 30, 1957, amended by the 9. ADR Amendment of August 9, 1990 (BGBl. II p. 838), Appendix A, Margin number 3731
- the ordinance regarding the national and international rail transport of hazardous commodities (Ordinance Regarding Hazardous Commodities, Rail, abbr. GGVE) of July 22, 1985, amended by the 3. Amendment to the Ordinance Regarding Hazardous Commodities, Rail of June 6, 1990 (BGBl. I p. 1001), Appendix, Margin number 1731.
- Regulations for International Rail Transport of Hazardous Commodities (RID-Regulations), Appendix I of Supplement B of the Agreement on International Rail Traffic (COTIF-Agreement) of May 9, 1980 (BGBl. 1985 II p. 566), amended by the 3. RID

amendment of May 3, 1990 (BGBl. I p. 461), Appendix, Margin number 1731.

3. **Manufacturer:**

Mallinckrodt Diagnostica B.V., NL-17562G Pellen

4. **Description of Capsule:**

An inactive end piece with the identification of the radiator is (laser) welded to one end of a [\*\*\*] steel cable consisting of 7 bundles of 7 cables each; the radiator lid is (laser) welded to the other end. A [\*\*\*]-cylinder with a diameter of 0.6 mm and a height of 3.5 mm is filled into a radiator tube with the length of 4.5 mm, a base of 0.4 mm, an external diameter of 1.1 mm and a wall of 0.2 mm; then the lid is attached (to the [\*\*\*]) and tightly fastened through laser welding. The overall length of the radiator is 1484 mm, its diameter is 1.05-1.10 mm. All components of the radiator, except the content of maximally 450 GBq (12cl) of metallic [\*\*\*], consist of [\*\*\*] high-grade metall AISI 316L.

5. **Diagram of Assembly:**

Nr. 080950 "Micro Selectron HDR" of January 1, 1991

This license consists of 2 pages of text and 1 diagram and it may be duplicated only in an unabridged form. Publication of licenses (including partial publications), references to analyses for purposes of advertisement and the [\*\*\*] of [\*\*\*] of the licenses require a revokable permission of the BAM in each case.

Page 2 of License D/0046/S (Rev. 2) of July 1, 1992

6. **Tests:** The radiator design that is to be evaluated here corresponds to very similar designs of the same manufacturer that were subjected to tests that resulted in licenses D/0046/S of July 19, 1990 and D/0046/S (Rev. 1) of February 14, 1990. On the one hand, the changes refer to the measurements of the radiator tube that has been shortened by 1 mm and that now shows a slightly altered thickness of the wall, and to the radioactive content that has been concentrated from 8 small to 1 large cylinder and that has been adjusted to the modified interior measurements of the radiator tube. On the other hand, the changes refer to the gradual transition from electronic beams to laser welding.

Four of five samples of the design that were filled with inactive indium were each verified with respect to the ISO classification

53221 regarding use as directed and also subjected to both the IAEA shock test (Safety Series No. 6, paragraph 608: one sample of design on lead base, flat impact of a shock cylinder of 1.4 kg mass after falling from a height of 1 m) and the IAEA heating up test (paragraph 610: one sample of design in a crucible furnace heated up to a temperature of 800° Celsius, leaving it for 10 minutes at this temperature, then gradual cooling down). The 9 m fall test (paragraph 607: fall of the radiator onto a rigid foundation) was abandoned because the stress it exerts on the radiator is relatively insignificant and similar design samples had already been subjected to fall tests without being damaged. Since the rigid part of the radiator is only 5 mm long and attached to flexible steel cables a bending test (paragraph 609) was neither necessary nor feasible.

Before and after the stress tests the radiator regions were carefully examined under a stereoscopic microscope (up to a 40fold enlargement) whereby minor plastic deformations were observed in the areas of the impact of the shock masses (IAEA paragraph 608 and ISO category of shocks #2, respectively: sample of design on steel base, flat impact of a shock cylinder with a mass of 50 g after falling from a height of 1 m). Since the air reservoir with its approximate free volume of 1/2 mm<sup>3</sup> is very small the common integral bubble tightness test through submersion in hot water could not be meaningfully conducted. Therefore, aside from the favorable visual tests described above, the only tests conducted were sensitive helium tightness tests in the critical areas of the radiator with the welded lids. For this purpose the test samples were undone near the ends of the Iridium filling. The parts with the welded radiator lids were inserted into tight drill holes in a 0.5 mm thick copper plate and tightly glued in place. Then they were tested for tightness by means of spraying the open side with Helium while a Helium mass spectrometer was attached to the exposed side with the weld seam. Within the parameters of the precision of our measurements of [\*\*\*] mbar [\*\*\*] no permeation of Helium was indicated. The radiator parts with the weld had therefore remained tight and have thus, in the evaluation of the BAM, passed all design tests (paragraph 613); decisive criterium: in case of solid and sparingly soluble content, standard Helium devices [\*] 10 [\*] mbar [\*\*\*].

#### 7. License:

On the basis of the results ascertained according to 6., the design described in 4. and 5. corresponds to the conditions according to 2. The admissible content is limited to 450 GBq [\*\*\*].

The Federal Agency for Research and Testing of Materials reserves the right to verify whether the reproduced radiators correspond to the licensed design.

For the time being, this license is valid for five years. It is to be submitted for review without prompting in time before the expiration of this period.

Laboratory 6.32  
"Radiation Protection and  
Tightness Testing"

(Seal)

Berlin, July 1, 1992  
Federal Agency for Research and  
Testing of Materials (BAM)  
Section 6.3  
"Nuclear Technology in the Testing  
of Materials and Radiation Protection"

Subject Specialist  
(signature)  
Dipl. Phys. M. Kowalewsky  
(Senior Executive Officer)

Section Head  
(signature)  
Prof. Dr. W. Görner  
(Senior Executive Officer)

NOV 19 1996

Shirley L. Green  
Vice President, Patient Services  
Harper Hospital  
3990 John R. Street  
Detroit, MI 48201

Dear Ms. Green:

Enclosed is Amendment No. 82 to your NRC Material License No. 21-04127-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
  - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

301987

4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;
  - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

S. Green

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prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By  
Evelyn R. Matson  
Nuclear Materials Licensing Branch

License No.: 21-04127-02

Docket No.: 030-02045

Enclosure: Amendment No. 82

DOCUMENT NAME: M:\03002045.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII <i>EM</i> <i>N</i>								
NAME	EMATSON:jaw								
DATE	11/18/96								

OFFICIAL RECORD COPY



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

October 29, 1996

Shirley L. Green  
Vice President Patient Services  
Harper Hospital  
3990 John R Street  
Detroit, MI 48201

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter Dated 10/08/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License                      ☒ Amendment                      ☐ Renewal  
☐ Termination                      ☐ Auth User (Amendment not required)  
☐ Other \_\_\_\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301987  
License No. 21-04127-02