MATERIALS LICENSE

Amendment No. 39

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.

301785

Licensee	
1. Butterworth Hospital	In accordance with letter dated August 23, 1996 3. License Number 21-00243-06 is amended in its entirety to read as follows:
2. 100 Michigan N.E. Grand Rapids, MI 49503	4. Expiration Date October 31, 2001
	5. Docket or Reference No. 030-01989

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 (excluding aerosols and generators)	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 (not to exceed 1 curie of I-131)
D. Any Byproduct material identified in 10 CFR 35.400	D. Any radiopharmaceutical 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

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SUPPLEMENTARY SHEET

License Number
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Docket or Reference Number
030-01989

Amendment No. 39

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
H. Cesium-137	H. Sealed sources (ORNL-RAMCO-50 or ISO-1000)	H. 3000 curies
I. Phosphorus-32	I. Any	I. 10 millicuries
J. Phosphorus-33	J. Any	J. 10 millicuries
K. Sulphur-35	K. Any	K. 10 millicuries

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding aerosols and generators).

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. To be used in an ACEL Gammacell 1000 irradiator for the irradiation of blood, blood products, biological or other samples except highly flammable or explosive items.

I., J. and K. To be used for in vitro laboratory research in the labeling of nucleic acids.

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SUPPLEMENTARY SHEET

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Docket or Reference Number
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Amendment No. 39

CONDITIONS

10. Location of Use: 100 Michigan N.E., Grand Rapids, Michigan; 1300 Michigan N.E., Suite 101, Grand Rapids, Michigan; and Lakeshore Area Radiation Oncology Center (LAROC), 12642 Riley Street, Holland, Michigan (strontium-90 ophthalmic applicator, Model RA-1A, Serial 529 only).

11. Radiation Safety Officer: Thomas J. Vitalis, M.S.

12. Authorized users:

    A. Robert W. Gillies, M.D., for material in 10 CFR 35.400.

    B. John H. Edlund, M.D., for material in 10 CFR 35.400.

    C. Thomas Vitalis, M.S., for cesium-137 irradiator.

    D. Marc G. Haidle, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

    E. Kenneth J. Gritter, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

    F. Jacquelyn Watson, M.D., for material in 10 CFR 35.400.

    G. Steven Waslowski, M.D., for material in 10 CFR 35.100, 35.200 and 35.500.

    H. Bradford W. Betz, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

    I. Thomas J. Monroe, Ph.D., for Subitems 6.I., 6.J. and 6.K. for in vitro laboratory research in the labeling of nucleic acids.

    J. Eric Buth, M.D., for material in 10 CFR 35.400.

    K. Michael Mahacek, M.D., for material in 10 CFR 35.400.

13. A. (1) The source(s) specified in Items(s) 7.H. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

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

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or 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, IL 60532, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by personnel designated by the Radiation Safety Officer, or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

14. The licensee shall maintain records of information important to safe and effective decommissioning at 100 Michigan N.E., Grand Rapids, Michigan per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

15. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

16. The procedures contained in AECL's instruction manual for the Model Gammacell 1000 device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-00243-06

Docket or Reference Number
030-01989

Amendment No. 39

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Applications dated July 11, 1991 and September 6, 1984; and

B. Letters dated October 11, 1991, May 13, 1992, June 19, 1992, November 19, 1992 January 29, 1993, March 8, 1994, January 31, 1995, February 9, 1995 (with attachments), March 15, 1995, May 4, 1995, April 22, 1996, July 2, 1996 and August 23, 1996 (excluding request for 90 day decay-in-storage of S-35).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 26, 1996

By Richard Warnick
Nuclear Materials Licensing Branch, Region III

COPY

55

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 3E 2B
Exp. Date: 20011031
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: BUTTERWORTH HOSPITAL
   Received Date: 960829
   Docket No: 3001989
   Control No.: 301785
   License No.: 21-00243-06
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 542085

3. COMMENTS

Signed D. Hensey
Date 9-30-96

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

1. Fee Category and Amount: 7C #440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 9/4/96

1996 SEP -3 AM 11:11

SEP 09 1996

Log Sep 1 III
Remitter
Check No. 542085
Amount #440
Fee Category 7C
Type of Fee Amdt
Date Check Rec'd 8/29/96
Date Completed 9/4/96
By: SC

Department of Pathology

Peter D. Van Vliet, M.D.
Director, Pathology and
Clinical Laboratories

M. Gerald Cioherty, M.D.
Associate Director, Pathology
and Clinical Laboratories

Harold J. Hommerson, M.D.
Richard A. Horvitz, M.D.
Carmel L. Davy, M.D.
Kim Alan Mills, M.D.
Gloria J. Kohut, M.D.
David M. Graham, M.D.
Yuki A. Hammers, M.D.
Staff Pathologists

Robert C. Fader, Ph.D.
Microbiologist

Phyllis Webb, Ph.D.
Immunologist

Butterworth
HOSPITAL

August 23, 1996

United States Nuclear Regulatory Commission
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

RE: Amendment to License No. 21-00243-06, Butterworth Hospital

Item 1

Please add room 1197 as an area of use for the use of radioactive materials. A diagram of this room is enclosed for your review. Upon approval of this room we move from our current area of use (room 1124) to the new room (room 1197) and will perform a close-out survey of room 1124.

Item 2

Please amend our license to allow us to decay-in-storage byproduct material with a physical half-life of less than **90 days**. This will allow us to decay-in-storage S-35 which has a half-life of 87.4 days.

The $440 amendment fee is enclosed.

If there are any questions regarding this amendment please contact Tom Monroe at 616-391-3026. Thank you for your cooperation in this matter.

Sincerely,

Doreen Schwartz
Vice President of Operations

/pkn

RECEIVED
AUG 2 9 1996
REGION III

PM: 8-28-96

100 Michigan, Northeast Grand Rapids, Michigan 49503 Phone: 616/391-1840 Fax: 616/391-1986

301785

NOV 27 1996

Thomas J. Vitalis, M.S.
Radiation Safety Officer
Butterworth Hospital
100 Michigan N.E.
Grand Rapids, MI 49503

Dear Mr. Vitalis:

Enclosed is Amendment No. 39 to your NRC Material License No. 21-00243-06 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 we have not authorized your request for 90 day decay-in-storage of S-35 per conversation with Tom Monroe, Director of Molecular Biology on November 25, 1996.

Please be advised that we cannot authorize you to release your old nuclear medicine space for unrestricted use (even by other members of your staff) until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

a. A diagram of your old facility with survey and wipe test results keyed to specific locations.

b. The name of the person performing the survey.

c. The date the survey was performed.

d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.

301785

e. Background readings

f. The date that the survey instrument was last calibrated.

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.

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, 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
Gidget Watson
Nuclear Materials Licensing Branch

License No. 21-00243-06
Docket No. 030-01989

Enclosure: Amendment No. 39

DOCUMENT NAME: M:\03001989.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									
NAME	GWatson:brt									
DATE	11/20/96 GW									

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME | DATE 11/25/96

O VISIT O CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.ETC.) | TELEPHONE NO.

Tom Monroe, Ph.D., Dir. Molecular Biology | Butterworth Hosp. | 616/391-3026

SUBJECT

License No. 21-00243-06

SUMMARY

I informed Dr. Monroe that I would approve the addition of room 1197 as an area of use and that I would not release the old area for unrestricted use until we received and reviewed the closeout survey.

I also informed Dr. Monroe that he would have to respond to several questions regarding the request for 90 day decay-in-storage of S-35. I informed him that I would fax these questions to him and that he could respond to Control No. 301785 with no additional fee. (SEE ~~Attached~~)

Dr. Monroe stated that he would respond accordingly.

ACTION REQUIRED

Midori Watson | SIGNATURE | 11/25/96

NAME OF PERSON DOCUMENTING CONVERSATION | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

DRAFT

ENCLOSURE 1

INFORMATION NEEDED IN AN AMENDMENT REQUEST
DECAY-IN-STORAGE OF RADIOACTIVE MATERIALS WITH HALF-LIVES
GREATER THAN 65 DAYS

The following paragraphs identify the information needed in an amendment request from a materials licensee to authorize decay-in-storage (DIS) of radioactive materials with half-lives greater than 65 days.

1. Identification of Waste to be Stored:

   a. Specify any possession limit increases needed for DIS radioactive materials.

   b. Identify the estimated maximum amount of radioactive material for DIS, both in terms of volume and activity, by radionuclide.

   c. Characterize the radioactive material for DIS:

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

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

      (3) Waste processing: Volume reduction, solidification or other treatment

      (4) Additional non-radiological properties of radioactive materials for DIS (if any): hazardous, biologic/pathogenic, corrosive flammable, etc.

   d. Describe the amount and type of radioactive materials currently being held for DIS.

   e. Identify any additional permits or approvals necessary for storage (i.e., EPA hazardous waste permit, State or local approvals, etc. or local approvals, etc.) and the status of each required approval.

   f. Describe the procedure to segregate the radioactive materials (i.e., liquid, solids, etc.).

[1] Review 10 CFR Part 61 for a reference (most DIS radioactive material will be Class A waste).

2. Physical Description of Storage Area:

a. Identify the location and provide a diagram of the DIS area which demonstrates where packages will be stored and how packages will be accessible for inspection purposes (address needs for shielding). Include the locations of waste processing equipment (if applicable), air sampling stations, effluents filters and any sources of flammable or explosive material.

b. Specify the maximum volume of radioactive materials for DIS that be stored in the proposed waste storage area and relate this to annual volume of waste generated.

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

d. Describe the measures to control access to the DIS area and thereby ensure security of the waste.

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

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

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

n. Describe vulnerability to other hazards such as tornado, hurricane, flood, industrial accident, etc.

3. Packaging and Container Integrity:

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

b. Describe your program for periodic inspections[2] of DIS Packages to ensure that they retain their integrity and containment.

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

[2] The minimum acceptable periodic inspection frequency should be performed monthly to quarterly, dependent on the type of radioactive material stored.

4. Radiation Protection:

   a. 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 Section 20.203.

   b. Describe your procedures for notification of and coordination with local fire, police and medical departments.

   c. Describe your system for maintaining records for accountability of waste in storage.

5. Disposal Procedures

   a. Describe your procedures for monitoring the waste to assure that it has decayed to background levels prior to disposal. As a minimum, your description should include these points:

      (1) Commitment to monitor the waste in a low background area.

      (2) Waste must be segregated by types of radionuclide and physical form of waste: solid, liquid or gas.

      (3) Waste must be held for decay for a minimum of 10 half-lives.

      (4) For each of the radionuclides, describe the instrumentation that will be used to monitor each isotope you wish to dispose of as indistinguishable from background.

      Note: A Pancake G.M. probe may be used to survey the surface (not the container) of the solid waste held for decay and liquid scintillation may be used to survey liquid waste held for decay.

      (5) Commitment to maintain records of these surveys as required under 10 CFR 20.

6. Training:

   a. Describe your program for training personnel in procedures for packaging, handling, placement, inspection, surveying and emergency response for DIS.

7. Financial Assurance:

   a. Review the relevant sections of Parts 30, 40 and 70 regarding financial assurance for 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

financial resources are or will be in place not only to only to decommission the licensed operation, but also to provide for the estimated costs of handling, transport and ultimate disposal of radioactive material for DIS.

7. 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 30.33(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.