NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 09

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, 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.

301673

Licensee	
1. Children's Hospital Medical Center of Akron	In accordance with letter dated July 19, 1996
2. One Perkins Square Akron, OH 44308-1062	3. License Number 34-09846-02 is amended in its entirety to read as follows:
	4. Expiration Date June 30, 2005
	5. Docket or Reference No. 030-18592

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. Iodine-131	C. Any iodine (capsules only) as included in 10 CFR 35.300 (excluding thyroid carcinoma therapy)	C. 30 millicuries
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Cesium-137	E. Sealed sources (ORNL-RAMCO-50 or ISO-1000)	E. Not to exceed 1,500 curies total
F. Chromium-51	F. Any	F. Not to exceed 3 millicuries
G. Sulfur-35	G. Any	G. Not to exceed 10 millicuries
H. Phosphorous-32	H. Any	H. Not to exceed 10 millicuries

2/1 NL 2/30 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-09846-02
Docket or Reference Number: 030-18592
Amendment No. 09

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 (excluding iodine-131 for thyroid carcinoma therapy).

D. In vitro studies.

E. To be used in an AECL Gammacell 1000, Model B self contained irradiator for the irradiation of blood, blood components, and other biological samples except flammable or explosive materials or for sterilization and/or research purposes.

F. through H. To be used for in vitro laboratory studies.

CONDITIONS

10. Location of Use: One Perkins Square, Akron, Ohio.

11. Radiation Safety Officer: Pranav K. Vyas, M.D.

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. Joseph A. Crawford, M.D.	10 CFR 35.100, 35.200, 31.11, and iodide treatment of hyperthyroidism and cardiac dysfunction.
B. Anthony Passalaqua, M.D.	10 CFR 35.100, 35.200, 31.11, and iodide treatment of hyperthyroidism and cardiac dysfunction.
C. Richard A. Kraus, M.D.	10 CFR 35.100, 35.200, and 31.11.
D. Jon L. Apati	cesium-137 irradiator.
E. Robert W. Novak, M.D.	cesium-137 irradiator.
F. John R. Waterson, M.D., Ph.D.	Items 6.D. and 6.F. through 6.H. for in vitro laboratory studies.

12. (Continued)

Authorized Users		Material and Use
G.	Donna C. M. Galehouse, Ph.D.	10 CFR 31.11, and Items 6.F. through 6.H.
H.	Stephanie P. Ryan, M.D.	10 CFR 35.100 and 35.200.
I.	Pranav K. Vyas, M.D.	10 CFR 35.100 and 35.200

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

C. Sealed sources need not be leak tested if:

(I) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

D. The leak 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, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-09846-02

Docket or Reference Number
030-18592

Amendment No. 09

D. (Continued)

decontaminated, repaired, or disposed of in accordance with Commission regulations. The 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, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

14. 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.

15. The procedures contained in AECL 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.

16. 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. Application dated November 21, 1994; and

B. Letters dated May 16, 1995, and October 25, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date August 13, 1996

By Evelyn R. Gibson
Nuclear Materials Licensing Branch, Region III

COPY

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: 20050630
FEE COMMENTS: CODE 23 3E ADDED 11/1
DECOM FIN ASSUR REQD: N

R9
MS-21

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CHILDREN'S HOSPITAL MEDICAL CENTER
RECEIVED DATE: 960731
DOCKET NO: 3018592
CONTROL NO.: 301673
LICENSE NO.: 34-09646-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 430.00
CHECK NO.: 599622

3. COMMENTS

SIGNED M. Mennan
DATE 8/21/96

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 AC
DATE 9/20/96

Log A49 3 III
Remitter
Check No. 599622 604328
Amount $430 $10
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 8/5/96
Date Completed 9/20/96
By: AC

SEP 23 1996

96 AUG -5 AM 11:08

Children's
Hospital Medical Center of Akron

DEPARTMENT OF RADIOLOGY
Godfrey Gaisie, M.D., Chairman
George E. Lerner, M.D.
Kenneth F. Swanson, M.D.
Richard A. Kraus, M.D.
Stephanie Ryan, M.D.

July 19, 1996

License Management Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Sir:

This constitutes an application for amendment of NRC Byproduct Material License No. 34-09846-02 issued to Children's Hospital Medical Center, Akron, Ohio.

Pranav K. Vyas, M.D. is to be added as an authorized user for uptake, dilution, and excretion studies (35.100) and for imaging and localization studies (35.200). Dr. Vyas was certified in Diagnostic Radiology with Special Competence in Nuclear Radiology by the American Board of Radiology in June 1995. A copy of the certificate is enclosed.

In addition, it is requested that Dr. Vyas be designated as the new Radiation Safety Officer for Children's Hospital Medical Center.

Enclosed is a check for $430.00 to cover the cost of this license amendment.

Sincerely,

William H. Considine
President

WHC/ss
Enclosure

PM: 7-30-96

One Perkins Square · Akron, Ohio 44308-1062

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Pranav Krishnakant Vyas, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this seventh day of June, 1995
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology
with
Special Competence in
Nuclear Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

Douglas Maynard, M.D.
President

William Jones, M.D.
Secretary-Treasurer

M. Paul Capp, M.D.
Executive Director

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

CHILDREN'S HOSPITAL MEDICAL CENTER
ATTN: WILLIAM H. CONSIDINE
PRESIDNET
DEPARTMENT OF RADIOLOGY
ONE PERKINS SQUARE
AKRON, OHIO 44308-1062

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-19-96

LICENSE NUMBER: 34-09846-02

CONTROL NUMBER: 301673

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$	$ 440.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(S) DUE	$ 440.00
PAYMENT RECEIVED	$ 430.00
AMOUNT DUE	$ 10.00

☐ Your request was received without the prescribed application fee.

☒ We received your Check No. 599622 in the amount of $ 430.00. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield SC		
SHIRLEY CRUTCHFIELD	8/6/96	

Distribution: OC/DAF/RF
Pending Fee File OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) Region 3

DATE: Aug 6, 1996

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

SEP 2 4 1996

William H. Considine, President
Children's Hospital Medical
Center of Akron
One Perkins Square
Akron, OH 44308-1062

Dear Mr. Considine:

Enclosed is Amendment No. 09 to your NRC Material License No. 34-09846-02 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.

301673

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
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No. 34-09846-02
Docket No. 030-18592

Enclosure: Amendment No. 09

DOCUMENT NAME: M:\03018592.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	NO						
NAME	ERMatson:brt							
DATE	08/13/96							

OFFICIAL RECORD COPY