NRC FORM 374
(7-94)

U.S NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 48

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.

301873

Licensee	
1. V. A. Medical Center	In accordance with letter dated September 20, 1996
2. 2215 Fuller Road Ann Arbor, MI 48105	3. License Number 21-00159-04 is amended in its entirety to read as follows:
	4. Expiration Date June 30, 1994
	5. Docket or Reference No. 030-01987

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 (not to exceed 1 curie of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources 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

9/1

210070

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-00159-04
Docket or Reference Number: 030-01987
Amendment No. 48

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
F. Gadolinium-153	F. Sealed Source (North American Scientific, Inc. Model 3601)	F. 4 sources, not to exceed 300 millicuries per source
G. Any byproduct material with Atomic Nos. 1 through 83, inclusive	G. Any	G. Not to exceed 150 millicuries per isotope, 20 curies total, except as listed below: Hydrogen-3, 1500 millicuries Iodine-123, 500 millicuries Iodine-125, 300 millicuries
H. Any byproduct material with Atomic Nos. 1 through 83, inclusive	H. Any	H. See Item 9.G. 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.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-00159-04

Docket or Reference Number
030-01987

Amendment No. 48

F. Two sources to be used in a ADAC Laboratories Transmission Line Source Housing VANTAGE device for medical radiography in humans. Two sources in shipping containers for replacement of the sources.

G. To be used for research and development as defined in 10 CFR Part 30, Section 30.4, including animal studies.

H. Possession incident to interim storage of waste beginning June 1, 1993 and ending December 31, 1995, in accordance with statements, representations and procedures contained in letter dated November 6, 1992.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2215 Fuller Road, Ann Arbor, Michigan and 3333 Glendale Avenue, Toledo, Ohio.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensees' Radiation Safety Committee, Milton D. Gross, M.D., Chairman.

B. The Radiation Safety Officer for this license is Melonie J. Payne, M.S.

C. The Alternate Radiation Safety Officer for this license is Joseph R. Wissing.

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

E. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

12. 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. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. 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.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. 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.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. 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 and the source shall be removed immediately from service and 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, 801 Warrenville Road, Lisle, Illinois 60532-4351, 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.

G. 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.

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

14. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, and 10 CFR 35.500, the licensee may use for any medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.

15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

17. Pursuant to 10 CFR 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.

18. Licensed material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this license.

19. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

    D. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-00159-04

Docket or Reference Number
030-01987

Amendment No. 48

20. The licensee shall maintain records of information related to decommissioning at location listed in item 2. of this license as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

21. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letter dated November 6, 1992 and September 28, 1995.

22. The licensee shall conduct a physical inventory every 3-months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59 and 10 CFR 35.400 and every 6 months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

23. Survey instruments shall be calibrated by any vendor authorized by the NRC or an Agreement State to perform such services.

24. 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 U.S. 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 received June 9, 1986; and

B. Letters dated March 16, 1989, March 30, 1989, September 17, 1990 (with attachments), November 6, 1990, April 11, 1991, May 31, 1991, August 1, 1991, November 6, 1992 (with attachments), September 28, 1995, (with attachments), November 17, 1995, December 13, 1995, and September 20, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/4/96

By Kevin D. Null
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: 02110
Status Code: 2
Fee Category: EX 7B 2B
Exp. Date: 19940630
Fee Comments: 170.11(A)(5)
Decom Fin Assur Reqd: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: V. A. MEDICAL CENTER
   Received Date: 960926
   Docket No: 3001987
   Control No.: 301873
   License No.: 21-00159-04
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: 0

3. COMMENTS

Signed D. Harvey
Date 9-27-96

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

1. Fee Category and Amount: _____

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

3. OTHER _____

FEE EXEMPT

Signed _____
Date _____

FEE EXEMPT

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
2215 Fuller Road
Ann Arbor MI 48105

SEP 20 1996

In Reply Refer To: 503/00R

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

Dear Mr. Null:

We would like to amend our current NRC Byproduct Materials License No. 21-00159-04. Our incumbent Radiation Safety Officer, Melonie J. Payne, intends to take a maternity leave which we anticipate to start in December of this year. Therefore, we believe it in our best interest to amend our license to include an alternate Radiation Safety Officer. Details regarding alternate selection and duties are enclosed for your review.

We would appreciate your timely review of this amendment should our Radiation Safety Officer need to start her maternity leave earlier than expected.

Please direct any questions or requests for additional information to Ms. Melonie Payne, Radiation Safety Officer, at the above address or telephone (313) 761-7916.

Sincerely,

EDWARD L. GAMACHE
Director

Enclosures

cc: Milton Gross, M.D., Chairman, Radiation Safety Committee (115)
Regional Radiation Safety Manager (132/RSM)
National Health Physics Director (115/HP)

FEE EXEMPT

RECEIVED
SEP 26 1996
REGION III

PM: 9-23-96

SEP 26 1996

301873

AMENDMENT REQUEST
September, 1996

NRC LICENSE # 21-00159-04

We believe it is in the best interest of this facility due to broadscope license and the nature of the animal and human research performed at our facility for there to be an alternate Radiation Safety Officer (RSO). The alternate RSO we have selected is Mr. Joseph R. Wissing. Mr. Wissing was previously listed as RSO on our license and his cirriculum vitae is enclosed for your review.

It is expected that the alternate RSO will act in the capacity of the RSO with the same responsibilities listed in our license. The Radiation Safety Committee (RSC) will expect the alternate RSO to act for the RSO in situations where the RSO is ill, is on sabbatical, is on vacation, is on maternity leave, etc., for periods of time that we anticipate not to exceed three months.

Assisting the alternate RSO in performing duties will be the Radiation Safety technician and the Chief Nuclear Medicine technologist.

JOSEPH R. WISSING

11101 Bethel Church Road
Manchester, MI 48108
(313) 428-1015 (Home)
(313) 930-5609 (Work)

EDUCATION:

University of Michigan
B.S. in biology, December 1984
Emphasis of Studies: Genetics/Molecular Biology

University of Michigan, School of Public Health
Masters Degree Program, Masters Degree in Public Health - Radiation Health Physics (in progress)

EMPLOYMENT:

12/92-Present **Regional Radiation Safety Program Manager**
Department of Veterans Affairs
40 Frank Lloyd Wright Drive
Central Regional Office (115HP)
Ann Arbor, MI 48105

Responsibilities:

Provide consultative support to 43 VHA medical centers located in 13 states concerning uses of all sources of ionizing radiation.

Perform medical center site visits to evaluate on site, individual medical center radiation safety program operations concerning all uses of ionizing radiation and compliance with applicable regulations.

Develop and implement standardized regional policies and procedures for medical center radiation safety program management.

Review all regional VA medical center NRC license applications, renewal submissions, and license amendments prior to submission to the NRC and provide guidance and remedial actions for all NRC violations.

Provide technical guidance for facilities regarding the Annual EPA Clean Air Act Emissions reporting requirement.

Investigate all reports of potential unsafe working conditions, potential radiation over exposures to employees as well as patients.

Provide and manage regional radiation safety training seminars concerning medical center management of radiation safety program operations.

1/89-12/92 *Radiation Safety Officer*
Veterans Affairs Medical Center
Department of Nuclear Medicine

Ann Arbor, MI 48105

Responsibilities:

Write, amend, and maintain the Nuclear Regulatory Commission Broad Materials License.

Supervise and monitor inventory of all radioactive materials received, transferred, and disposed.

Quality control and calibration of radiation detection equipment used in Nuclear Medicine and Research Service.

Monitoring and management of all Nuclear Medicine radioactive waste.

Monitoring and evaluating radiation safety protocols throughout all services of the medical center.

Monitoring and management of therapy patients treated with high doses of radioiodine.

Designing and implementing new health physics records and filing systems.

Responsible for developing and writing new Radiation Safety Manual.

12/88-12/88 *Research Associate I*
University of Michigan Medical Center
Department of Internal Medicine
Division of Nuclear Medicine
Ann Arbor, MI 48109-0028

Responsibilities:

Interim Director of Clinical Radiolabeling Facility.

Perform all radioiodine chemistry labeling and quality control procedures of monoclonal antibodies and proteins.

Prepare sterile pyrogen free iodinated monoclonal antibodies for human diagnostic and therapeutic studies.

Train and supervise new personnel involved with radioiodination of monoclonal antibodies and proteins.

Writing, documenting, evaluating laboratory protocols involving radiochemistry with iodine in laboratory, implementing data acquisition and filing system.

Summarizing and writing up data analysis of experiments performed for publications, presentations, and laboratory meetings.

Involved in coordination of patient studies concerning inter/intra-university and outside corporate studies for human diagnostic and therapeutic research.

Designed radiolabeling facility for Program Project Grant for Nuclear Medicine research.

Laboratory Supervisor of Radiation Safety Procedures

Write, update and maintain Radiation Control Service license for use of radioactive materials in the laboratory for animal and human use.

Supervise and train all new personnel safety techniques concerning handling and use of radioactive materials in the laboratory.

Responsible for personnel dosimetry monitoring of all personnel working in laboratory.

Supervise and monitor radioactive waste storage and disposal. Update protocols and maintain log of waste disposal.

Monitoring, calibrate and repair as needed all radiation detection equipment.

04/88-12/88 *Assistant Health Physicist*
University of Michigan Medical Center
Department of Internal Medicine
Division of Nuclear Medicine
Ann Arbor, MI 48109-0028

Responsibilities:

Quality control of radiation detection equipment used in Nuclear Medicine.

Monitoring and management of all Nuclear Medicine radioactive waste.

Monitoring and evaluating radiation safety protocols in Nuclear Medicine.

Monitoring and management of therapy patients treated with radioiodine.

Designing and implementing new health physics records and filing systems.

PUBLICATIONS:

1. Wahl RL, Wissing JR, Kaminski MS: Isotype switch variant anti-idiotype monoclonal antibodies: Comparative radiolabeling and in vitro binding. J Nucl Med.

2. Wahl RL, Leibert M, Fisher S, Sherman P, Jackson G, Laino L, Wissing J: Radioimmunotherapy of human ovarian carcinoma xenografts: Preliminary evaluation. Proceedings of AACR 28:384, 1987.

3. Wahl RL, Johnson J, Liebert M, Wissing JR, Boland R: Intraperitoneal monoclonal antibody therapy of intraperitoneal colon carcinoma xenografts. Proceedings of AACR 29:509, 1988.

4. Wahl RL, Wissing JR: Inhibition of autoradiolysis of radiolabeled monoclonal antibodies by cryopreservation. Submitted to the Society of Nuclear Medicine 36th Annual Meeting, St. Louis, MO, June 13-16, 1989.

OCT 0 4 1996

Edward L. Gamache, Director
Department of Veterans Affairs
Medical Center
2215 Fuller Road
Ann Arbor, MI 48105

Dear Mr. Gamache:

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 Branch at (630) 829-9887.

Sincerely,

Original Signed By
Kevin G. Null
Nuclear Materials Licensing Branch

License No. 21-00159-04
Docket No. 030-01987

Enclosures: As stated

DOCUMENT NAME: M:\03001987.CL6
To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	DNMS/RIII									
NAME	KGNULL:jaw	C								
DATE	10/4/96									

OFFICIAL RECORD COPY

301873

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REG. N III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 30, 1996

Melanie J. Payne
Radiation Safety Officer
V. A. Medical Center
2215 Fuller Road
Ann Arbor, MI 48105

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 09/20/96)

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 X 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. 301873
License No. 21-00159-04