



North Ottawa Community
Health System

May 7, 2008

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Amendment to License No. 21-13963-01, North Ottawa Community Hospital.

Please amend our license to add Lynn S. McCurdy, M.D. as authorized user of 10 CFR 35.100, 35.200 and 35.300. A copy of the Radioactive Material Permit from the United States Air Force is enclosed for your review.

Thank you for your cooperation in this matter. If you have any questions, please contact our consulting physicist, Dawn Edwards at 734-662-3197.

Sincerely,

Shelleye J. Yaklin, President/CEO
North Ottawa Community Health System

RECEIVED MAY 16 2008

General Information
616.847.3600
www.noch.org

Urgent Care Center
1091 S. Beacon Blvd., Grand Haven, MI 49417
616.604.0096 • Fax 616.604.0095

North Ottawa Community Hospital
1309 Sheldon Rd. Grand Haven, MI 49417
616.842.3600 • Fax 616.847.5621

In-Home Care Nursing
1500 S. Despelder, Grand Haven, MI 49417
616.847.9090 • Fax 616.847.9166

North Ottawa Care Center
1615 S. Despelder, Grand Haven, MI 49417
616.842.0770 • Fax 616.847.842.0783

In-Home Care Equipment
1310 Wisconsin St., Ste. 100, Grand Haven, MI 49417
616.846.0360 • Fax 616.846.6643

Hospice of North Ottawa Community
1515 S. Despelder, Grand Haven, MI 49417
616.846.2015 • Fax 616.846.7227

In Home Care Pharmacy
1309 Sheldon Rd., Grand Haven, MI 49417
616.847.5504 • Fax 616.847.5676

RADIOACTIVE MATERIAL PERMIT
USAF RADIOISOTOPE COMMITTEE

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Pursuant to the authority stated in AFI 40-201, Managing Radioactive Materials in the USAF, and in reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer and store radioactive materials listed below, and to use this material for the purpose and at the places listed below. This document is not a valid permit unless it is endorsed by a representative of the USAF Radioisotope Committee.

1. ORGANIZATION 10 MDG/SG 4102 PINION DR, STE 100 USAF ACADEMY CO 80840-4000		2. PERMIT NO. CO-01236-02/05AFP	3. AMENDMENT NO. 5
		4. EXPIRATION DATE 30-Jun-2009	
		5. DOCKET NO. 030-01236	
6. PERMIT RSO: RITTER, TIMOTHY		7. ALTERNATE PERMIT RSO: MAFI, TEVITA	
8. RADIOACTIVE MATERIAL (Element and Mass Numbers)	9. CHEMICAL/PHYSICAL FORM (NSN or Model Number) (* Denotes sealed sources)	10. MAXIMUM QUANTITY AUTHORIZED	
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed	
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed, except Xenon-133 gas which is not to exceed 160 milli-curie	
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 3 curie	
D. Any accelerator produced diagnostics radio-pharmaceutical, except Xenon-127	D. Any IND or FDA approved radiopharmaceutical	D. As needed	
E. Any accelerator produced diagnostic calibration standard	E. Any	E. As needed; not to exceed 22 milli-curie per source	
11. AUTHORIZED USE A. Medical use for uptake, dilution, and excretion studies permitted by 10 CFR 35.100 B. Medical use for imaging and localization studies permitted by 10 CFR 35.200 C. Medical use for which a written directive is required and per 10 CFR 35.300 D. Medical use (FDA approved procedure) E. Calibration			
12. AUTHORIZED USERS			
NAME		AUTHORIZED USE	
Michael McCollum, M.D.		Items 11 A, B, C, D, E	
Donald M. Medina, M.D.		Items 11 A, B, C, D, E	
Richard Karsh, M.D.		Items 11 A, B, C (excluding iodine-131 for thyroid carcinoma treatment), D, E	
Phillip Middleton, M.D.		Items 11 A, B, D, E	
William P. Abraham, M.D.		Items 11 A, B, C, D, E	
John McArthur, M.D.		Items 11 A, B, C, D, E	
Richard W. Bentley, M.D.		Items 11 A, B, C (Oral administration of iodine-131), D, E	
Mark W. Sankey, M.D.		Items 11 A, B, C, D, E	
Robert J. Schimmel, M.D.		Items 11 A, B, C, D, E	
Lynn S. McCurdy, D.O		Items 11 A, B, D, E	
Anton Nesse, M.D.		Items 11 A, B (except Xenon-133), C (Oral administration of iodine-131), D, E	
CONDITIONS			
13. The authority for this permit is US Nuclear Regulatory Commission (NRC) Master Material License No. 42-23539-01AF issued to the USAF Radioisotope Committee and AFI 40-201, Managing Radioactive Materials in the USAF.			
14. The Permittee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," Part 20, "Standards for Protection Against Radiation," and Part 35, "Medical Use of Byproduct Material," except that all reports required by those parts must be made to the USAF Radioisotope Committee Secretariat. In addition, the Permittee shall comply with all applicable Air Force Regulations and Instructions, and directives of the USAF Radioisotope Committee necessary to insure compliance.			
15. Permitted material shall be used or stored only at the Permittee's medical facility: building #4102, rooms 1284, 1285, 1285A, 1286, 1288, 1289, 1816 (pathology), and operating rooms 1, 2, 3, 4, 5 located at The United States Air Force Academy CO.			

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16. Individuals designated in writing as authorized users, as defined in 10 CFR 35.2, may be reviewed and approved by the Permittee's current authorized users and permit RSO. Documentation must be submitted to the USAF Radioisotope Committee Secretariat within 30 days per 10 CFR 35.14. Individuals that meet the appropriate training and experience criteria established in 10 CFR 35, Subparts B, D, and E, must be approved by the USAF Radioisotope Committee Secretariat before the individual may be designated as an authorized user and radiation safety officer.
17. A. In addition to the possession limits in item 10, the Permittee shall further restrict the possession of sealed sources of permitted byproduct to quantities below 10E10 times the quantity specified in 10 CFR 30 Appendix B for establishing decommissioning financial assurance. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to 10E10 times the applicable quantity specified in 10 CFR 30, Appendix B, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

 B. Notwithstanding the authorizations in items 8, 9, and 10 of this permit, the Permittee will further limit the unsealed radioactive materials possessed under this permit to those isotopes with half lives less than 120 days.
18. The Permittee shall notify AFMOA/SG3PR within 30 days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug (IND)" for any material authorized by this permit.
19. The Permittee shall not acquire permitted material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
20. Specific calibration, transmission, and reference sources covered under 10 CFR 35.65 do not need to be listed in item 8.
21. Sealed sources containing permitted material shall not be opened or removed from devices by the Permittee.
22. A. (1) Each sealed source acquired from another person and containing permitted 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 permitted sealed source is exempt from such leak tests when the source contains 100 micro-curie or less of beta and/or gamma emitting material or 10 micro-curie or less of alpha emitting material.

 (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or concentration.

 B. Each sealed source containing permitted material, other than Hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

 C. Test sample(s) shall be collected by the Permittee and forwarded to the Air Force Institute for Operational Health (AFIOH/SDR, 2350 Gillingham Dr, Brooks-City Base TX 78235-5103) or to any individual authorized by USNRC or Agreement State license or USAF or USN permit to evaluate leak tests for others.

 D. The leak test shall be capable of detecting the presence of 0.005 micro-curie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device for which the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of micro-curie and maintained for inspection by the NRC, the USAF Radioisotope Committee Secretariat, or the Medical Directorate of the Air Force Inspection Agency.

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E. If the test required by Subsection A. or B. of this condition reveals the presence of 0.005 micro-curie or more of removable contamination, the Permittee shall immediately withdraw the sealed source from use and shall decontaminate it and either repair or dispose of it in accordance with NRC regulations and Air Force directives. A report shall be filed within 5 days of the test with the USAF Radioisotope Committee Secretariat (AFMOA/SG3PR, 110 Luke Ave Room 405, Bolling AFB DC 20032-7050) describing the equipment involved, the test results, and the corrective action taken.

23. The Permittee shall conduct a physical inventory every 6 months to account for all sealed sources received and possessed under this permit. The records of the inventories shall be maintained for 3 years from the date of the inventory and made available for inspection by the NRC, the USAF Radioisotope Committee Secretariat, or the Medical Directorate of the Air Force Inspection Agency, and shall include: a) inventory date, b) model and serial number of device or source, c) radionuclide and activity, d) device or source location, and e) signature of the permit RSO certifying the inventory accuracy.

24. The Permittee may hold any radioactive material authorized by this permit with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity (10 CFR 35.92(a)), provided:

A. Before disposal, the waste shall be surveyed at the container surface with the appropriate survey instrument 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 obliterated or removed.

B. A record of each such disposal permitted under this permit condition shall be retained for three 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.

25. The Permittee may transport permitted material in accordance with the provisions of 10 CFR 71, "Packaging of Radioactive Material for Transport" and 49 CFR 170 through 189, "Transportation" subject to any host nation restrictions under Status of Forces Agreements.

26. Transfer of permitted material may only be to a USAF or USN Radioactive Material Permittee or to an NRC or Agreement State License holding a valid authorization to receive the sources. The permitted materials must be disposed of in accordance with AFI 40-201.

27. Information: SSgt James E. Brown has begun 1 year RSO training as of 28 Aug 2006.

28. Except as specifically provided otherwise by this permit, the possession and use of radioactive material described in item 8 of the permit shall be in accordance with statements, representation, and procedures contained in the following documents:

DOCUMENT	SUBJECT	DATE
10 MDG/SGSAR (Application)	Application for Material License	01-March-2003
AFMSA/SGPR (Memo)	Deemed Timely Filled Letter	21-March-2003
10 MDG/SGSARN (Memo)	Amendment - Change RSOs and update AUs	09-September-2003
10 MDG/SGSAR (e-mail)	Amendment - Add Xe-133 and other RAM	28-May-2004
AFMSA/SGPR (Permit)	Permit Document	20-June-2004
10 MDG/SGSAR (Memo)	Amendment - change RSOs, update AUs	30-December-2004
10 MDG/SG (Memo w/ atch)	Amendment - change RSOs, update AUs	12-August-2005
10 MDG/SGSAR (Memo w/ atch)	Amendment - change RSOs, update AUs, add use locations, re-ordered permit conditions (AFMOA/SGPR)	08-September-2006
10 MDG/SGSAR (e-mail)	Amendment - Add AU authorized use for Dr. Ness, typographical corrections, increase max. quantity for item 8.E	20-March-2007
10 MDG/SGSAR (e-mail w/Atchs)	Amendment - Add/Remove AUs; update room numbers	29-June-2007

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The Nuclear Regulatory Commission's regulations and United States Air Force directives shall govern the Permittee's statements in applications or letters, unless the statements are more restrictive than the regulations and directives.

FOR THE USAF RADIOISOTOPE COMMITTEE:

Date 25 July 2007

By Robert A. Rodgers
ROBERT A. RODGERS, Maj, USAF, BSC
Deputy Chief, Radiation Protection Division
USAF Radioisotope Committee Secretariat
Air Force Medical Operations Agency
Office of the Surgeon General



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

25 July 2007

MEMORANDUM FOR 10 MDG/SG
10 MDSS/SGSARN
IN TURN

FROM: AFMOA/SG3PR
110 Luke Avenue, Room 405
Bolling AFB DC 20032-7050

SUBJECT: Amendment Request (29 June 2007), USAF Radioactive Material Permit No. CO-01236-02/04AFP,
Docket No. 030-01236

To the Permit RSO: Please make a copy for your files.

We have received the permit amendment request dated 29 June 2007 for permit No. CO-01236-02/4AFP. Attached is amended permit No. CO-01236-02/5AFP reflecting the following changes: Add/delete authorized users, update room numbers, and removal of permit condition 27 due to a large radiologist staff and on-site medical physicist that serves as Permit Radiation Safety Officer (RSO). Major Timothy Ritter is the RIC approved permit RSO and TSgt Tevita Mafi is the RIC approved alternate permit RSO. Please review the permit carefully to ensure that it authorizes the sources and uses requested, and that you understand its conditions and limitations. The inspection category for this permit is 02120, the inspection frequency for this permit is every 3 years, unannounced; this permit expires 30 Jun 2009.

Thank you for your comments regarding permit condition 22.A(2). We will consider your suggestion during the next review of our database permit condition statements. Condition 18 will be retained in the permit. The permit application requested authorization for Investigational New Drug (IND) or Food and Drug Administration (FDA) approved radiopharmaceutical use. Note that IND is synonymous with "Notice of Claimed Investigational Exemption for a New Drug." If the Academy desires to utilize an IND, then the FDA has specific requirements related to the IND application that must first be completed prior to clinical use. I direct you to 21 CFR Part 312 Investigational New Drug Application for more details. Specifically, 21 CFR 312.44 discusses termination of IND. The RIC places condition 18 to insure it is informed of the IND activity status.

If you have any questions regarding permit No. CO-01236-02/5AFP, then please contact me at DSN 297-4309; robert.rodgers-02@pentagon.af.mil or Ms Nicole Allen; nicole.allen@pentagon.af.mil. Additional contact information: telefax is DSN 754-8089; web page address is https://kx.afms.mil/rad_prot; cell phone for receiving after-duty-hours Incident/Accident Reports is 703-340-0819.

Robert A. Rodgers

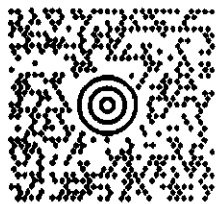
Robert A. Rodgers, Maj, USAF, BSC
Deputy Chief, Radiation Protection Division
USAF Radioisotope Committee Secretariat
Air Force Medical Operations Agency
Office of the Surgeon General

Attachment:
Permit No. CO-01236-02/5AFP

cc:
HQ AFIA/SGI (Lt Col Adams)
USNRC, Region IV (Ms Browder)

FROM:

ADMIN-S. TRAVIS
(616) 842-3600
NORTH OTTAWA COMMUNITY HOSPITA
1309 SHELDON RD.
GRAND HAVEN MI 49417-2488

1 LBS 1 OF 1**IL 603 9-03****SHIP TO:**

REGION III, OFFICE OF MATLS. LICENS
UNITED STATES NUCLEAR REG. COMM.
STE. 210
2443 WARRENVILLE ROAD
LISLE IL 60532-4352

UPS GROUND

TRACKING #: 1Z 464 443 03 4034 0047



BILLING: P/P

WS 10.0.45 HP DeskJet 1278.0A 04/2005

Fold here and place in label pouch