

8505 Arlington Boulevard
Suite 320
Fairfax, VA 22031
(703) 641-0500

**Cardiac Diagnostic
Services of Virginia**

MS 16
J-4
45-25533-01
03035466

Fax

To: Lisette	From: Stella Li-Thieman
Fax: (610) 337-5269	Pages: 13
Phone: (610) 337-5237	Date: 1/18/2008
Re: Mail Control # 141229	CC:


Urgent
 For Review
 Please Comment
 Please Reply
 Please Recycle

Lisette,

Please find enclosed the information that you requested, per our conversation this morning.

Please contact me if you have any further questions.

Thank you,



Stella Li-Thieman

141229

NMSS/RGN1 MATERIALS-002



MINNESOTA DEPARTMENT OF HEALTH

PAGE 1 OF 8 PAGES

RADIOACTIVE MATERIALS LICENSE

Pursuant to Minnesota Statute 144.12 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 radioactive materials 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 rules. This license is subject to all applicable rules and orders of the Minnesota Department of Health including the Minnesota Radioactive Materials Rules, Chapter 4731, now or hereafter in effect, and to any conditions specified below.

Licensee 1. Mayo Clinic 2. 200 First Street SW Rochester, Minnesota 55905	In accordance with the documents listed in Item 30, the Minnesota Department of Health Radioactive Materials License is issued to read as follows: 3. License Number: 1047-201-55 4. Expiration Date: May 31, 2012 Program Code Primary: 2110 Secondary: 2230	
5. Byproduct, Source, Special Nuclear and/or Natural Occurring or Accelerator Produced Radioactive Material A. Any radioactive material with atomic numbers 3-83, inclusive B. Americium-241 C. Hydrogen-3	6. Chemical and/or Physical Form A. Any B. Sealed source (registered pursuant to 32.210 of 10 CFR Part 32 or an Agreement State equivalent rule) C. Foil	7. Maximum Amount that Licensee May Possess At Any One Time Under This License A. 1 curie per radionuclide. Total possession not to exceed 10 curies except as listed below: Carbon-11, 4 curies; Fluorine-18, 9 curies; Hydrogen-3, 5 curies; Iodine-131, 5 curies; Molybdenum-99, 60 curies; Rhenium-188, 3 curies; Samarium-153, 10 curies; Technetium-99 ^m , 60 curies; Tungsten-188, 3 curies Xenon-133, 2 curies B. Four sources not to exceed 100 millicuries each C. 2 curies



RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

- | | | |
|--|--|--|
| <p>5. Byproduct, Source, Special Nuclear and/or Natural Occurring or Accelerator Produced Radioactive Material</p> <p>D. Any radioactive material with atomic numbers 3-83, inclusive</p> <p>E. Cesium-137</p> <p>F. Cesium-137</p> <p>G. Cesium-137</p> <p>H. Gadolinium-153</p> <p>I. Cesium-137</p> <p>J. Iridium-192</p> | <p>6. Chemical and/or Physical Form</p> <p>D. Sealed source (registered pursuant to 32.210 of 10 CFR Part 32 or an Agreement State equivalent rule)</p> <p>E. Sealed source (J.L. Shepherd & Associates Model 78-10)</p> <p>F. Sealed source (ORNL RAMCO-50)</p> <p>G. Sealed source (J.L. Shepherd Model 6810 or ORNL Model A-0096)</p> <p>H. Sealed sources (registered pursuant to section 32.210 of 10 CFR Part 32 or an Agreement State equivalent rule)</p> <p>I. Sealed source (Nordion International, Inc. Model No. C-3001)</p> <p>J. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)</p> | <p>7. Maximum Amount that Licensee May Possess At Any One Time Under This License</p> <p>D. No single source to exceed 1.5 curies, except as listed below; total possession not to exceed 10 curies. Iodine-125, 2.0 curies; Palladium-103, 2.0 curies; Iridium-192, 4.0 curies</p> <p>E. Two sources not to exceed 260 curies each</p> <p>F. One source not to exceed 400 curies</p> <p>G. Not to exceed 5,000 curies per source set</p> <p>H. 12 sources not to exceed 500 millicuries each</p> <p>I. 6075 curies total</p> <p>J. Two sources. One not to exceed 12 curies. One not to exceed 8 curies.</p> |
|--|--|--|



RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

- | | | |
|---|--|--|
| <p>5. Byproduct, Source, Special Nuclear and/or Natural Occurring or Accelerator Produced Radioactive Material</p> <p>K. Iridium-192</p> | <p>6. Chemical and/or Physical Form</p> <p>K. Sealed sources (Varian VS-2000)</p> | <p>7. Maximum Amount that Licensee May Possess At Any One Time Under This License</p> <p>K. Two sources. One not to exceed 12 curies. One not to exceed 9 curies.</p> |
|---|--|--|

8. AUTHORIZED USE

- A - B. Medical diagnosis, therapy, and research in humans. Research and development as defined in 4731.0100, including animal studies, student instruction, and instrument calibration.
- C. To be used in gas chromatographs.
- D. Medical use as defined in 4731.0100 (which includes diagnosis, therapy, and research in humans); animal studies and instrument calibration.
- E. For use in J.L. Shepherd & Associates Mark I-25 irradiator for medical and radiobiological research.
- F. For use in an Isomedix, Inc. Gammator 50B (AECL Gammacell 10) irradiator for biomedical research.
- G. To be used in J.L. Shepherd Model Mark I-25 irradiator for the irradiation of medical and biological samples.
- H. To be used for automatic attenuation correction on gamma cameras.
- I. To be used in a Nordion International, Inc. Model Gammacell 3000 Elan Type II irradiators for the irradiation of medical and biological samples.
- J. One source for medical use, as permitted by 4731.4463, in a Nucletron MicroSelectron-HDR Model 105.999 remote afterloading brachytherapy device. One source (not to exceed 12 curies while stored pending installation) in a shipping container for source replacement. The source may also be used for physics calibrations and intercomparison studies.
- K. One source for medical use, as permitted by 4731.4463, in a Varian Medical Systems-HDR VariSource Model 200t remote afterloading brachytherapy device. One source (not to exceed 11 curies while stored pending installation) in a shipping container for source replacement. The source may also be used for physics calibrations and non-human use research.**

**RADIOACTIVE MATERIALS LICENSE**

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

CONDITIONS

9. A. Licensed material shall be used only at the licensee's facilities located at the Mayo Clinic Rochester campus, Rochester, Minnesota.
- B. Licensed material authorized by 4731.4432, 4731.4434 (excluding Xenon-133 and generators), 4731.4460, and Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction may be used at temporary jobsites of medical care facilities anywhere in the State of Minnesota where the Minnesota Department of Health maintains jurisdiction for regulating the use of licensed material.
- C. **Licensed material listed in Subitems 5. J. and 5. K. may be used at the Charlton or Eisenberg buildings, located on the Mayo Foundation campus, Rochester, Minnesota. The two HDR units will be stored separately. One unit to be stored at Charlton Subway 350G and one unit to be stored at Charlton Building, Room S259, located on the Mayo Foundation campus, Rochester, Minnesota.**
10. The Radiation Safety Officer for this license is Richard J. Vetter, Ph.D.
11. A. The use of licensed material in or on humans shall be by an authorized user as defined in 4731.0100, Subpart 24.
- B. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee, Robert J. Witte, M.D., Chairperson. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
12. Authorized users of radioactive material in medical applications must meet the training and experience in 10 CFR 35 subparts D, E, F, G and H, and the recentness of experience requirements in Minnesota Rules, part 4731.4415. In addition, the requirements for the following users (as defined in 10 CFR 35.2) apply:
- A. 10 CFR 35.50 for Radiation Safety Officer (RSO)
- B. 10 CFR 35.51 for Authorized Medical Physicists
- C. 10 CFR 35.55 for Authorized Nuclear Pharmacists
13. In addition to the possession limits in Item 7, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 4731.3150, which require consideration of the need for an emergency plan for responding to a release of licensed material, and shall further restrict the possession of unsealed licensed material to less than 10^5 times the applicable limits in 4731.2800 Subp. 3, as specified in 4731.3080.
14. For sealed sources not associated with uses authorized in 4731.4400 to 4731.4527, the following conditions apply:

**RADIOACTIVE MATERIALS LICENSE**

SUPPLEMENTARY SHEET

LICENSE No. 1047-201-55

- A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as specified by the certificate of registration.
- 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 three 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. Sealed sources need not be tested if they contain only Hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- E. Sealed sources not designed to emit alpha particles may be stored for a period of no more than three years without being tested for leakage and/or contamination. When sealed sources are removed from storage for use or for transfer to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerel) 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 MDH. If the test reveals the presence of 0.005 microcurie (185 becquerel) or more of removable contamination, a report shall be filed within five days with the Minnesota Department of Health and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with MDH regulations.
- G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services.
15. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by the US Nuclear Regulatory Commission.
16. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism that prevents the foil temperature from exceeding 325 degrees Centigrade.
17. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

**RADIOACTIVE MATERIALS LICENSE**

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

18. Pursuant to 4731.0700 to 4731.0840, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, and transfer up to 999 kilograms of depleted uranium contained as shielding material.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided.
 - A. 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.
 - B. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
 - C. A record of each disposal permitted under this License 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.
21. Pursuant to 4731.2095 Subpart 3 and 4731.2410, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in 4731.2750 Subpart 7.
22. Pursuant to 4731.2410, the licensee is authorized to dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than that of the values in Column 2 of 4731.2750 Subpart 7. For Hydrogen-3, Carbon-14, Aluminum-26, Chlorine-36, Silver-108m, Niobium-94, Iodine-129, Technetium-99, and Thallium-204, the concentration can be no greater than one-tenth of the value in Column 2 of 4731.2750 Subpart 7. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.
23. Experimental animals administered licensed materials or their products shall not be used for human consumption.
24. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71 "Packaging and Transportation of Radioactive Material." Nothing in this license condition applies to the extent that the person is subject to regulations of the NRC.
25. This license does not authorize commercial distribution of licensed material.

**RADIOACTIVE MATERIALS LICENSE**

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

26. 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 US Nuclear Regulatory Commission or an Agreement State to perform such services.
27. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:
- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
 - B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
 - C. Have room monitors installed that will:
 - (1) Operate at all times when the irradiator is in use; and
 - (2) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
 - (3) Detect any radiation leaking from the irradiator door; and
 - (4) Be visible to the irradiator user when he is next to the irradiator; or
 - D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
 - (1) Determine the radiation at the irradiation door when the door is closed; and
 - (2) Check for any increase in radiation levels each time the irradiator door is opened.
 - E. Immediately stop the use of the irradiator and notify the MDH by telephone if abnormal levels of radiation or any malfunction of the irradiator is detected; and
 - F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the commission or an Agreement State to perform such services.
28. The procedures contained in J. L. Shepherd, ORNL instruction manual for the Models 7810, 6810, RAMCO-50, A-0096 devices shall be followed and a copy of these manual shall be made available to each person using or having responsibility for the use of each device.
29. The licensee must comply with the requirements described in the Minnesota Department of Health letter dated November 14, 2005 and the attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee must complete implementation of said requirements by May 13, 2006 or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later.



RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET

LICENSE NO. 1047-201-55

30. 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. The Minnesota Department of Health's rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rules.

A. NRC application dated November 28, 2001 (excluding reference to the Quality Management Program).

B. Letters to NRC dated October 9, 2003, May 11, 2005, and November 15, 2005.

C. Letter to NRC dated September 8, 2005.

D. MDH amendment request dated September 6, 2006 and October 16, 2006.

For the Minnesota Department of Health

Date: 10/26/06

By: [Signature] Radioactive Materials Group

Approval

Date: 10/26/06

By: [Signature] Radiation Control Unit Supervisor

Concurrence

Date: 10/26/06

By: [Signature] Section Manager

JSL

Still need copy of Lic

Dr. Luy



January 7, 2008

TO: Whom It May Concern

In accordance with University Broad Scope Medical License – License # 25-1323-01, the University Radiation Safety Committee, University of Wisconsin Madison, approved Charles K. Stone, M.D. as an Authorized User in:

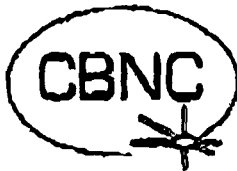
- 1. Nuclear cardiology study.
- 2. Metabolic research studies.

Victor Goretsky
 Victor Goretsky, RSO
 University of Wisconsin - Madison

**Environmental Health & Safety
 Division of Facilities Planning and Management
 Radiation Safety Office**

University of Wisconsin—Madison
 30 North Murray Street
 Madison Wisconsin 53715—1327

<http://www.ephs.wisc.edu/safety>
 Phone (608) 265-5000
 Fax (608) 262-6767



Certification Board of Nuclear Cardiology

19562 Club House Road • Montgomery Village, Maryland 20886
Tel: +240.631.8151 • Fax: +240.631.8152
administration@cbnc.org • www.cbnc.org

BOARD OF DIRECTORS

Representing the American Society of Nuclear Cardiology

- Edward P. Ficare, PhD
- Milena J. Hertzlova, MD
- William A. VanDecker, MD

Representing the American College of Cardiology

- Kenneth A. Brown, MD

At Large Directors

- Ogkunte D. Akiribaboye, MD, MPH
- James A. Arighi, MD
- Robert J. Gropler, MD
- Christopher L. Hanson, MD
- Thomas A. Holly, MD
- Howard C. Lawa, MD
- Sally Schwarz, RPh, MS, BCNP

Dawn M. Edgerton, MA
Executive Director

Verification of Certified Status

To Whom It May Concern:

This letter confirms that the following individual is certified in nuclear cardiology by the Certification Board of Nuclear Cardiology.

Name: Charles K. Stone, M.D.
Year of Certification: October 2000 (Valid Through December 2010)
Certificate No.: 1889

Attested by: _____
Dawn M. Edgerton, Executive Director

Date: August 15, 2007

UW Authorized Users, Nuclear Pharmacists, Medical Physicists

Name	Clinic	Title	Modality ¹
WILSON, Michael	Nuclear Medicine / PET	MD	A, B & C
PERLMAN, Scott	Nuclear Medicine / PET	MD	A, B & C
BIANCO, J. A.	Nuclear Medicine / PET	MD	A, B & C
* STONE, Charles ²	Nuclear Cardiology / PET	MD	C
HELLMAN, Charles	Nuclear Cardiology	MD	C
HAGEN, Tamara	Nuclear Cardiology	MD	C
CHANG, Su Min	Nuclear Cardiology	MD	C
KULHANEK, Jan	Nuclear Cardiology	MD	C
MONCHER, Karen	Nuclear Cardiology	MD	C
LEE, John	Nuclear Cardiology	MD	C
BRJING, Timander	Nuclear Cardiology	MD	C
HAMMES, Richard	Nuclear Medicine / PET	Nuclear Pharmacist	A, B & C
JOAS, Lori	Nuclear Medicine / PET	Nuclear Pharmacist	A, B & C
KNISHKA, Scott	Nuclear Medicine / PET	Nuclear Pharmacist	A, B & C

¹Modality

A: Unsealed radioactive material, written directive not required (i.e., diagnostic studies, uptake, dilution and excretion studies; imaging & localization studies)

B: Unsealed radioactive material, written directive required (i.e., oral administration of NaI < 33 mCi; oral administration of NaI > 53 mCi; Y-90 Zevalin; Sr-89 / Sm-153)

C: Nuclear cardiology studies

²Dr. Stone is also authorized metabolic research studies approved by the Radioactive Drug Research Committee

Name	Clinic	Title	Modality ¹
HARARI, Paul	Radiation Oncology	MD	1, 2, 3, 4, 5, 6, 7
METHA, Minesh	Radiation Oncology	MD	1, 2, 3, 4, 5, 6, 7
RITTER, Mark	Radiation Oncology	MD	1, 2, 3, 4, 5, 6, 7
STEEVES, Richard	Radiation Oncology	MD	1, 2, 3, 4, 5, 6, 7
HOWARD, Steve	Radiation Oncology	MD	1, 2, 3, 4, 5, 6, 7
MAHLER, Peter	Radiation Oncology	MD	1, 2, 3, 6, 7
FERNANDES, Patrick	Radiation Oncology	MD	1, 2, 3, 6, 7
WELSH, James	Radiation Oncology	MD	1, 2, 3, 5, 6, 7
PATEL, Rakesh	Radiation Oncology	MD	1, 2, 3, 5, 6
BRADLEY, Kristin	Radiation Oncology	MD	1, 2, 3, 5
KHUNTIA, Deepak	Radiation Oncology	MD	1, 2, 3, 5
JARADAT, Hazim ²	Radiation Oncology	Medical Physicist	1 ¹ , 2, 3, 4, 5
MACKIE, Rock ²	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6
NELSON, Ian A ²	Radiation Oncology	Medical Physicist	1, 2, 4
SMILOWITZ, Jennifer ²	Radiation Oncology	Medical Physicist	1, 2, 3
ODAU, Heath	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6, 7
ORTON, Nigel	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6
PALIWAL, Bhudatt	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6, 7
DAS, Rupak	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6, 7
THOMADSEN, Bruce	Radiation Oncology	Medical Physicist	1, 2, 3, 4, 5, 6, 7

¹Modality

1. LDR (Cs-137, Ir-192, I-125 / Pd-103 seeds)

2. HDR (Ir-192)

3. Beta-Cards (Sr-90 Intravascular Brachytherapy)

¹Limited to I-125 / Pd-103

²Not currently practicing brachytherapy

4. Iortex (I-125 brain device)

5. Sm-153 / Sr-89 (radiopharmaceutical bone)

6. Y-90 SirSphere

7. Sr-90 Eye Applicator (calibrated before use)

Bruce R. Thomadsen
Bruce R. Thomadsen
Chairman, UW Radiation Safety Committee

6/19/06
Date

Wisconsin License # 25-1323-01



January 4, 2008

Manuel D. Cerqueira, M.D.
Chairman, Nuclear Medicine
Professor of Radiology, Cleveland Clinic Learner
College of Medicine of Case Western Reserve

Regarding: Ketan Trivedi, MD

To Whom it May Concern,

Ketan Trivedi, MD, completed level II training in nuclear cardiology during his cardiology fellowship from July 1998 to June 2001 at Georgetown University Hospital under my Preceptorship for 6 months. I was listed as an authorized user at Georgetown University Hospital broad scope license under Nuclear Regulatory Commission license number #46-00990-01. As a result of this training he meets the requirements for the use of radionuclides under CFR 35-100, 35-200.

Dr. Trivedi is competent to independently function as an authorized user under CFR 35-100, 35-200.
uses.

A handwritten signature in black ink that reads 'Manuel D. Cerqueira, MD'.

Manuel D. Cerqueira, MD