GE Healthcare

GE Healthcare

June 17, 2007

NMSB2

U.S Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region 1
King of Prussia, Pa. 19406

03031972

RE: Amendment to Material License 29-28341-02MD

Dear Sir/Madame

Please amend license condition 11.A to include the following individual;

Diana R. Levine R.Ph.

This individual is a registered pharmacist in the State of New Jersey and an authorized Nuclear Pharmacist, please see document # MD-05-148-01 from the state of Maryland.. Please see copies of her New Jersey pharmacist license and Radioactive Material License from the state of Maryland.

Should you have additional questions please feel free to contact me at 973-533-9109.

Sincerely,

Anthony Ponterio

Anthony Ponterio R.Ph.
Radiation Safety Officer

RECEIVED
REGION 1
2007 JUN 21 PM 1:26

General Electric Company
1 Naylon Place
Livingston, NJ 07039
U.S.A.

T 973 533 9109
F 973 533 1116

140706

NMSS/RGN1 MATERIALS-002

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

Diana R. Lavane [redacted]

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacist

05/31/2007 TO 04/30/2009
VALID

28RI03138000
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

ACTING DIRECTOR

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

State of Maryland

DEPARTMENT OF THE ENVIRONMENT

RADIOLOGICAL HEALTH PROGRAM

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Maryland Radiation Act, 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 material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

Licensee	
1. Cardinal Health 2. 3737 Old Georgetown Road Baltimore, Maryland 21227	3. License No.: MD-05-148-01 4. Expiration date: July 31, 2008 5. Amendment No.: **31** (Code 02500)

6. Radioactive material element & mass number:	7. Chemical and/or physical form:	8. Maximum amount of radioactivity which licensee ma possess at any one time:
A. Molybdenum-99	A. Any Mo-99/Tc-99m generator, manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to COMAR 26.12.01.01 § C.28(j) or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations.	A. 300 Curies
B. Technetium-99m	B. Sodium Pertechnetate and products labeled in accordance with the manufacturer's instructions.	B. 200 Curies
C. Xenon-133	C. Unit dose containers and/or saline as a pharmaceutical.	C. 5 Curies
D. Iodine-131	D. Any	D. 3 Curies
E. Thallium-201	E. Any form listed in COMAR 26.12.01.01 §G.31	E. 2 Curies
Fluorine-18	F. Fluorine FDG	F. 1 Curie

G.	Any radioactive material, except Tc-99m and I-131, listed in COMAR 26.12.01.01 §G.29.	G.	Any form listed in COMAR 26.12.01.01 § G.29.	G.	25 Curies
H.	Any radioactive material, except Tc-99m, Xe-133, Tl-201, I-131, and F-18 listed in COMAR 26.12.01.01 §G.31.	H.	Any form listed in COMAR 26.12.01.01 §G.31.	H.	25 Curies
I.	Any radioactive material, except I-131, listed in COMAR 26.12.01.01 §G.35.	I.	Any form listed in COMAR 26.12.01.01 §G.35.	I.	2.5 Curies
J.	Any radioactive material listed in COMAR 26.12.01.01 § C.22(l).	J.	Pre-packaged *in-vitro* diagnostic kits.	J.	25 millicuries
K.	Uranium (depleted in the isotope U-235)	K.	Metal enclosed in stainless steel.	K.	300 kilograms
L.	Any sealed source listed in COMAR 26.12.01.01 § G.18.	L.	Sealed source	L.	No single source to exceed 20 millicuries; Total possession less than 70 millicuries.
M.	Yttrium – 90	M.	Any	M.	500 millicuries

License Conditions

9. Authorized Use

A. Elution of Tc-99m Pertechnetate. Redistribution of unused Mo-99/Tc-99m generators.
B. Distribution and preparation of reagent kits and radiopharmaceuticals. Distribution and use as check, calibration, or reference source. Storage of contaminated vials, syringes and needles returned by customers.
C. Distribution to authorized recipients in individually prepackaged quantities.
D. Compounding, dispensing, and distribution of radiopharmaceuticals to authorized recipients.
E. Distribution of prepared radiopharmaceuticals to authorized recipients.
F- I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
J. Distribution of prepackaged *in-vitro* diagnostic test kits.

License No.: MD-05-148-01	Amendment Number: 31

License Conditions

K. Shielding for Mo-99/Tc-99m generators.
L. Calibration/reference source. Distribution as calibration/reference source to authorized recipients.
M. For compounding, dispensing and distribution to authorized recipients.

10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address as is required by COMAR 26.12.01.01 §D.1301.

11A. The radiation protection program shall be under the supervision of Julie Zadecky, R.Ph.

11B. Radioactive material shall be used by, or under the supervision of:

Blaise Lachowicz, R.Ph., Ray D. Courtney, R.Ph., Craig C. Barlow, R. Ph., Howard Stoops, R.Ph. and Melissa Goodhart, R.Ph., Steve Herlich, R.Ph., Michael Badrian, R.Ph., Lysa Baylin, R.Ph., Thomas Jandora, R.Ph., Andrew Cote, R.Ph., Kristen Sipe, R.Ph., John Schlosberg, R.Ph., Julie Zadecky, R.Ph., Melissa Goodhart, R. Ph., **Diana** R. Levine, R.Ph., **Brent C. Griggs, R.Ph. and Craig Schury, R.Ph.**

11C. At least one individual named in Condition 11B shall be physically present at the authorized place whenever licensed material is being used.

12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation."

13A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

13B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.

13C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.

13D If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 1800 Washington Boulevard, Suite 750, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.

License Conditions

13E Test for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.

13F. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

13G. 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 tested within six months prior to the date of use or transfer.

14. The licensee shall conduct a physical inventory every six- (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

15. Sealed sources containing radioactive material shall not be opened.

16. Only residual radioactive waste resulting from shipments from MidAtlantic Isotopes under this license may be collected from the licensee's customers and disposed of in accordance with the procedures, statements and representations in renewal application dated April 26, 2001.

17A. Radiopharmaceuticals distributed for human use shall be either:

1. Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (NDA), or
2. Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

17B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators and reagent kits for which FDA has accepted an IND shall be dispensed:

1. In accordance with the directions provided by the sponsor of the IND, and.
2. Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug. The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

License Conditions

18. The licensee shall elute generators and process radioactive material with reagent kits in accordance witl instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

19. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the Program Manager, Radiological Health Program, 1800 Washington Boulevard, Suite 750, Baltimore, Maryland 21230.

20. Sealed sources containing radioactive material shall not be opened.

21A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

21B. The licensee shall not distribute for human use technetium-99m that, at the expiration date and time shown on the package label, contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. The expiration date and time shown on the package label shall be such that the limit above is not exceeded for any single patient dose. The limit for molybdenum-99 contamination represents a maximum value and molybdenum-99 contamination should be kept as low as reasonably achievable below this limit.

21C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limit specified in Item 21B. above are detected.

21D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

1.) The licensee shall maintain for inspection by the Department records of the results of each tes performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2.) Records described in Subitem (1) above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

22. Food and beverage containers shall not be discarded in radioactive or normal trash containers in licensee's areas utilizing radioactive materials.

23. Transportation of radioactive material in the State of Maryland shall be in compliance with Part T, Section T.5 "Transportation of Licensed Material" of COMAR 26.12.01.01.

License No.: MD-05-148-01	Amendment Number: 31

License Conditions

24A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Additionally, the licensee shall not falsify, tamper with, or render inaccurate any monitoring device or method.

24B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.

25. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:

A. Renewal application dated September 11, 2000.
B. Revised renewal application dated April 26, 2001.
C. Facsimile dated June 29, 2001.
D. Facsimile and attachment dated July 12, 2001.
E. Compliance response dated October 24, 2001, which shall be incorporated into this license.
F. Letter with attachments dated May 7, 2002, adding Santander Bornacelly R.Ph.
G. Letter with attachment dated May 16, 2003, changing the Radiation Safety Officer and deleting a user.
H. Letter with attachment dated July 8, 2003 adding user.
I. Letter with attachment dated January 5, 2004 adding user.
J. Letter with attachment dated March 15, 2004 adding user
K. Letter with attachment dated June 7, 2004, adding Howard Stoops, R.Ph.
L. Letter with attachment dated July 12, 2004, changing RSO and adding user.
M. Letter with attachment dated August 24, 2004, adding authorized users.
N. Letter with attachment dated September 13, 2004 adding Melissa Goodhart, R. Ph. and deleting users
O. Letter dated October 13, 2004, with remodeled floor plan of facility.
P. Letter dated June 22, 2004, changing ownership.
Q. Letter dated July 19, 2004, containing answer to the 6 Questions.
R. Facsimile received December 29, 2004 dated July 15, 2004, providing additional information on ownership change.
S. Letter with attachment dated May 11, 2005, changing Julie Grbavac to Julie Zadecky and making her the RSO.
T. Facsimile dated July 15, 2005, authorizing Paul Gotti and Willie Rigits to represent the Company.

State of Maryland

DEPARTMENT OF THE ENVIRONMENT

RADIOLOGICAL HEALTH PROGRAM

RADIOACTIVE MATERIAL LICENSE

License No.: MD-05-148-01	**Amendment Number:** 31

License Conditions

U. Compliance response dated October 16, 2005 (date corrected), which shall be incorporated into this license.

V. Letter dated January 23, 2006, with attachments adding Ms Levine to 11B. Request to add Authorized Nuclear Pharmacist(s) by reference to other license(s) is denied.

W. Letter dated March 16, 2006, with attachments, adding ANPs.

COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

April 17, 2006

Roland G. Fletcher, Manager III

Radiological Health Program

dkm

This is to acknowledge the receipt of your letter/application dated

6/17/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-28341-02MD

☑ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140706.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader