



Allegiance
HEALTH

April 7, 2010

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

Re: License No. 21-00258-06, Allegiance Health

1. Please remove Randall Bardwell, CNMT as Radiation Safety Officer. He is no longer at our facility.
2. Add Mohammad Asad, M.D. as Radiation Safety Officer. Effective immediately he has been named our temporary Radiation Safety Officer pending NRC approval. Dr. Asad is an authorized user on our license and was previously the Radiation Safety Officer at Espanola Hospital in New Mexico. The agreement state license number is for Espanola Hospital is MI073-31. A copy of that license with his name listed as Radiation Safety Officer is enclosed.

A copy of the RSO / management letter of understanding is also enclosed.

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

Sincerely,

Administrator
Robyn D. Pulliam, MS, BSEd, ARAT(R)
Director of Imaging Services
Allegiance Health

205 N. EAST AVE. • JACKSON, MI 49201 • (517) 788-4800 • AllegianceHealth.org



Allegiance
HEALTH

**RSO / EXECUTIVE MANAGEMENT
LETTER OF UNDERSTANDING**

April 7, 2010
Mohammad Asad, M.D.
Allegiance Health
205 North East Avenue
Jackson, MI 49201

Re: Radiation Safety Officer / Executive Management
Letter of Understanding

Dear Dr. Asad:

You have been appointed the temporary Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.

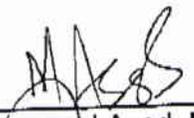
Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:

- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
 1. Identify radiation safety problems;
 2. Initiate, recommend, or provide corrective actions;
 3. Stop unsafe operations; and,
 4. Verify implementation of corrective actions.

Our signatures noted below will attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,


Executive Management
Robyn D. Pulliam
Director of Imaging Services


Mohammad Asad, M.D.
Radiation Safety Officer

205 N. EAST AVE. • JACKSON, MI 49201 • (517) 788-4800 • AllegianceHealth.org

Apr. 12. 2010 7:03AM



Radiation Control Bureau
State of New Mexico
Environment Department
1190 St. Francis Drive, 87505-4173
PO Box 26110



Santa Fe, New Mexico 87502-6110
Phone (505) 476-3236 Fax (505) 476-3232
<http://www.nmenv.state.nm.us/nmrcb/home.html>

October 16, 2006

Mohammad Asad, M.D.
Española Hospital
P. O. Box 129
Española, NM 87532

Dear Dr. Asad:

Carefully review the contents and assure a complete understanding of all conditions in the attached New Mexico Radioactive Material License and immediately report any errors or omissions to the Radiation Control Bureau. This license is amended to delete license item I, Xenon-133, and to add four AU for all licensed RAM.

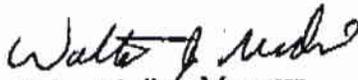
The New Mexico radioactive material licensee is required to be familiar with applicable parts of 20.3 NMAC. Copies of these regulations are available through the internet at:

www.nmenv.state.nm.us/nmrcb/home.html

A move to a different location requires you to notify and receive authorization from this Department at least thirty days in advance. Any sale or transfer of licensed material must be in accordance with 20.3.3.317.B. NMAC. All individuals receiving licensed material must possess a current U.S. NRC or Agreement State license.

You are required to possess a copy of this license at all work locations within New Mexico. Should you have any questions, please call me at (505) 476-3236.

Sincerely,


Walter Medina, Manager
Radiation Control Bureau



Radiation Control Bureau
State of New Mexico
Environment Department
1190 St. Francis Drive, 87505-4173
PO Box 26110



Santa Fe, New Mexico 87502-6110
Phone (505) 476-3236 Fax (505) 476-3232
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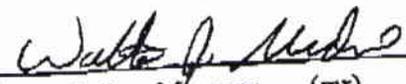
RADIOACTIVE MATERIAL LICENSE

Pursuant to Sections 74-3-1 through 74-3-16 NMSA 1978, and 20.3.3 NMAC, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated in this license; and to use said radioactive material(s) for the purpose(s) and at the place(s) designated herein. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect, of the New Mexico Environment Department and to any conditions specified herein.

1. License Name Española Hospital	2. License Number MI073-31
3a. Address P. O. Box 129 Española, NM 87532	3b. Actual Location of Operation 1010 Spruce Street Española, New Mexico 87532
4. Telephone (505) 753-7111	5. Expiration Date April 30, 2011

Date: October 16, 2006

For the New Mexico Environment Department


Walter Medina, Manager (mr)
Radiation Control Bureau

Attachments:

- 1) Radioactive Material Specifications
- 2) Authorized Use(s) and License Conditions

MI073-31

ATTACHMENT 1 - RADIOACTIVE MATERIAL SPECIFICATIONS



LICENSE NUMBER MI073-31

6. RADIOACTIVE MATERIALS (element and mass number)	7. FORM (chemical or physical)	8. MAXIMUM QUANTITY (Licensee may possess at any one time)
A. Any radioactive material listed in Groups I & II of Schedule C, Subpart 3, New Mexico Radiation Protection Regulations.	A. As unit doses, any radiopharmaceutical as indicated in Subpart 3, Schedule C, Groups I & II, New Mexico Radiation Protection Regulations.	A. As necessary for uses authorized in Sub-item 9 A. at address in Items 3a & 3b above.
B. Molybdenum 99.	B. Molybdenum 99/technetium 99m (Any generator approved by U.S. FDA and licensed for distribution by the U.S. NRC or Agreement State).	B. Not to exceed 2.5 curies total.
C. Technetium 99m.	C. Any listed in a U.S. FDA approved NDA.	C. As required.
D. Cobalt 57.	D. Sealed source (North American Science, Model A6002).	D. One source not to exceed 5.68 millicuries.
E. Cobalt 57.	E. Sealed source (CIS Model EGAG90).	E. One source not to exceed 5.84 millicuries.
F. Cobalt 57.	F. Sealed source (Dupont NES Model 206).	F. One source not to exceed 5.3 millicuries.
G. Cobalt 57.	G. Sealed source (Any model number approved by the U.S. NRC or Agreement State and listed in the Sealed Source and Device Registry).	G. One source not to exceed 20 millicuries.

ATTACHMENT 1 - RADIOACTIVE MATERIAL SPECIFICATIONS



LICENSE NUMBER MI073-31

6. RADIOACTIVE MATERIALS (element and mass number)	7. FORM (chemical or physical)	8. MAXIMUM QUANTITY (Licensee may possess at any one time)
H. Cesium 137.	H. Sealed source (Any model number approved by the U.S. NRC or Agreement State and listed in the Sealed Source and Device Registry).	H. One source not to exceed 250 microcuries.
I. Iodine-123.	I. Sodium Iodide.	I. As needed.
J. Technetium 99m.	J. DTPA.	J. Not to exceed 100 millicuries.

END OF THIS SECTION



ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-31

- 9. Authorized use:
 - A. For any diagnostic procedure listed in 20.3.331 NMAC, Schedule C, Groups I & II.
 - B. For use in the production of pertechnetate in accordance with the U.S. FDA approved package insert.
 - C. Any diagnostic use as specified in the respective U.S. FDA approved NDA or IND package insert.
 - D. through H. For use as a calibration source for dose calibrator.
 - I. For use in diagnostic thyroid uptake and imaging.
 - J. For use in ventilation studies with Biodex Radioaerosol Delivery System.
- 10. The licensee shall comply with the provisions of 20.3.3, 20.3.4, 20.3.7, and 20.3.10 NMAC.
- 11. The Secretary of the Department or the Secretary's authorized representatives shall be allowed to enter the premises and inspect the radiation related activities at all reasonable times. Failure of the licensee to admit the Secretary or the Secretary's authorized representatives shall constitute grounds for issuance of an immediate cease and desist order.
- 12. Thirty (30) days before vacating or relinquishing possession or control of the premises, the licensee shall notify the Department in writing of the intent to vacate and the address of relocation.
- 13. The licensee shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation. Records of the review shall be maintained for inspection by the Department.
- 14.A. The Radiation Safety Officer for this license is Mohammad Asad, M.D.
- 14.B. 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	Radioactive material described in Sub-items:
David Williams, M.D.	A. through J.
Mohammad Asad, M.D.	A. through J.
Bruce A. Legler, M.D.	A. through J.
Fredrick Akiya, M.D.	A. through J.
Duncan W. Lill, M.D.	A. through J.
Ihn P. Lee, M.D.	A. through J.
Jay Torres, M.D.	A. through J.

14.C. The use of radioactive material in or on humans shall be by a physician.



ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-31

15. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license provided the visiting physician:

15.A. Has the prior permission of the hospital administrator and its Radiation Safety Committee (RSC).

15.B. Is specifically named as a user on a State of New Mexico Radioactive Material License authorizing human use;

15.C. Performs only those procedures for which he is specifically authorized by a State of New Mexico Radioactive Material License; and

15.D. The licensee maintains for inspection by the Department, copies of the written permission specified in (A) above for five (5) years.

16.A. Each sealed source containing licensed material, other than hydrogen 3, with a half-life greater than thirty days and in any form other than gas, shall be tested for contamination and leakage 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, a sealed source received from another person shall not be put into use until tested.

16.A.(1) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak test when the source contains 100 microcuries or less of beta and gamma emitting material or 10 microcuries or less of alpha emitting material.

16.A.(2) 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 six months prior to the date of use or transfer.

16.B. 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 the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.

16.C. 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 days of the test with the New Mexico Environment Department, Radiation Control Bureau, P.O. Box 26110, Santa Fe, New Mexico 87502-6110, describing the equipment involved, the test results and the corrective action taken.

Attachment 2 (Page 2 of 4)



New Mexico Environment Department, Radiation Control Bureau

ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-31

- 16.D. Tests for leakage and contamination shall be performed by the manufacturer or by other persons specifically authorized by the Department to perform such services.
17. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed under the license. The records of the inventories shall be maintained for three 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, the date of the inventory, the name of the individual making the inventory, the manufacturer, the model number, and the serial number.
18. All incidents shall be reported to the Department in accordance with 20.3.4.452 NMAC.
- 19.A. Technetium 99 separated from molybdenum 99 either by elution of a molybdenum 99/technetium 99m generator or by an extraction process, shall be tested to detect and quantify molybdenum 99 activity prior to administration to patients.
- 19.B. The licensee shall not administer to patients technetium 99m containing more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99 at the time of administration. The limits for molybdenum 99 contamination represent maximum values and molybdenum 99 contamination should be kept as low as reasonably achievable below these limits.
- 19.C. 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 limits.
- 19.D. Personnel performing tests to detect and quantify molybdenum 99 contamination shall be given specific training in performing these tests prior to conducting such tests.
- 19.E. The licensee shall maintain for three (3) years records for inspection by the Department the results of each test performed to detect and quantify molybdenum 99 contamination and records of training given to personnel performing these tests.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- 20.A. Effected radioactive waste shall be held for decay a minimum of ten half-lives.
- 20.B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with the appropriate radiation detection survey meter set at its most sensitive scale and with no interposed shielding.
- 20.C. All radiation labels shall be removed or obliterated prior to disposal as normal waste.
- 20.D. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

Attachment 2 (Page 3 of 4)



New Mexico Environment Department, Radiation Control Bureau

ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-31

21. Except as otherwise provided by this license, radioactive material to be administered to humans shall be procured in pre-packaged, pre-calibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay. (e.g., identity, quality, purity, sterility, and non-pyrogenicity.)

22. Biological products labeled with radionuclides or kits used to prepare such products shall be procured from a supplier who holds a **unsuspended or unrevoked license** by the Secretary of the Department of Health, Education, and Welfare to propagate, manufacture, prepare, label, or distribute the products.

23. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of 10 CFR, Part 71, "Packaging and Transportation of Radioactive Material." A properly marked shipping container of the type supplied with the device shall be used whenever the device is shipped by commercial carrier.

24. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6., 7., and 8., of the license in accordance with statements, representations and procedures contained in, referenced in, or enclosed with the documents listed below. The most recent statements, representations, and procedures shall govern if they conflict with previously submitted documents. The New Mexico Radiation Protection Regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

* Application with attachments dated April 24, 2006, signed by JoJo Valdez, RT(R), Director of Radiology;

* Letter with attachments dated September 25, 2006.

