

March 27, 2008

United States Nuclear Regulatory Commission

Region III, Materials Licensing
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

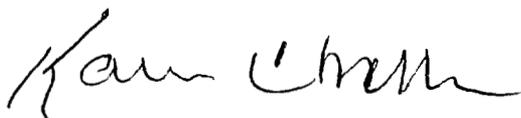
RE: Amendment to NRC License
NRC License No. 21-00258-06
W.A. Foote Memorial Hospital

Please amend our license to reflect the following changes:

1. Please add Dr. Mohammad Asad, M.D. to our license as an authorized user for 10 CFR 35.100 and 35.200. A copy of the state of New Mexico license, listing him as an authorized user is enclosed.
2. Please remove Dr. Marc B. Renner, M.D. from our license as an authorized user for 10 CFR 35.100, 35.200, and 31.11.

Thank you for your cooperation with this matter. If you have any questions or require additional information please contact our physics consultant, Laura Luna, at (734) 662-3197.

Sincerely,



Karen Chaprnka
Executive Administration

RECEIVED APR 08 2008



GARY E. JOHNSON
GOVERNOR

State of New Mexico
Environment Department
RADIATION CONTROL BUREAU
1190 St. Francis Dr., 87505
P.O. Box 26110, 87502-6110
Santa Fe, New Mexico
Telephone (505) 476-3236
Fax (505) 476-3232



PETER MAGGIORE
SECRETARY

<http://www.nmenv.state.nm.us/nmrcb.home.html>

August 7, 2002

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

Dear Dr. Asad:

Please carefully review the content of your enclosed New Mexico Radioactive Material License. Immediately report any errors or omissions to the Radiation Control Bureau. When requesting future license amendments, please include license name and number to ensure the correct license is amended.

A 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. Post enclosed form NMED045 in an area where it can be easily reviewed by all employees.

This license entitles the licensee to possess and use licensed material only at the locations named in New Mexico. Use of licensed material in other Agreement States, or on land falling under federal jurisdiction, must be in accordance with requirements imposed by these external jurisdictions.

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.

The licensee is subject to an annual fee as per 20.3.16 NMAC, due and payable on the anniversary of the date of issue of this license, 4/30. Should you have any questions, please call me at (505) 476-3236.

Sincerely,

William M. Floyd, Program Manager
Radiation Control Bureau



GARY E. JOHNSON
GOVERNOR

State of New Mexico
Environment Department
RADIATION CONTROL BUREAU
1190 St. Francis Dr., 87505
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 **RADIOACTIVE MATERIAL LICENSE**

Pursuant to Sections 74-3-1 through 74-3-16 NMSA 1978, and 20 NMAC 3.1, Subpart 3, 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 Espanola Hospital	2. License Number MI073-26
3a. Address P. O. Box 129 Espanola, NM 87532	3b. Actual Location of Operation 1010 Spruce Street Espanola, New Mexico 87532
4. Telephone (505) 753-7111	5. Expiration Date April 30, 2006

Date: August 7, 2002

For the New Mexico Environment Department


William M. Floyd, Program Manager (mr)
Radiation Control Bureau

Attachments:

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

MIC73-25

ATTACHMENT 1 - RADIOACTIVE MATERIAL SPECIFICATIONS



LICENSE NUMBER MI073-26

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 MI073-26

6. RADIOACTIVE MATERIALS
(element and mass number)

7. FORM
(chemical or physical)

8. MAXIMUM QUANTITY
(Licensee may possess at
any one time)

H. Cobalt 57.

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.

END OF THIS SECTION



New Mexico Environment Department, Radiation Control Bureau

Attachment 1 (Page 2 of 2)

ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-26

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 F. For use as a calibration source for dose calibrator.
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. Radioactive material shall be used by David Williams, M.D., Mohammad Asad, M.D. or Bruce A. Legler, M.D.
- 14.C. The use of radioactive material in or on humans shall be by a physician.
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

Attachment 2 (Page 1 of 5)



New Mexico Environment Department, Radiation Control Bureau

ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-26

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.(1) 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.(2) 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.(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 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 Protection Program, P.O. Box 26110, Santa Fe, New Mexico 87502-6110, describing the equipment involved, the test results and the corrective action taken.

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.



New Mexico Environment Department, Radiation Control Bureau

Attachment 2 (Page 2 of 5)

ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-26

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 99m per dose 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. Effectuated 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.

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.



ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-26

- 23.A. Subject radioactive materials shall be used only for clinical trials conducted in strict accordance with the FDA approved IND.
- 23.B. The licensee shall maintain an orderly file of all documentation required by the protocol and shall make the file available to the Department upon request.
- 23.C. The licensee shall obtain the informed consent of all human subjects participating in the investigation.
- 23.D. The licensee shall notify promptly the Radiation Protection Program and the sponsor of any adverse reaction attributable to the investigational radiopharmaceutical.
- 23.E. IND radiopharmaceuticals shall be used only by the sponsor approved investigator and only after specific written approval of the sponsor. Such documentation shall be available for inspection by the Department.
- 23.F. The expression "IND" shall be interpreted to mean only a "Notice of Claimed Investigational Exemption for New Drug" prepared in the format designated in "Form ED1571" as described in Section 130.3 Title 21, Code of Federal Regulations.
24. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage (DIS) before disposal in ordinary trash provided:
- 24.A. Effectuated radioactive waste shall be held for decay a minimum of ten half-lives.
- 24.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.
- 24.C. All radiation labels shall be removed or obliterated prior to disposal as normal waste.
- 24.D. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
25. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transportation Under Certain Conditions." A properly marked shipping container of the type supplied with the device shall be used whenever the device is shipped by commercial carrier.
26. 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



ATTACHMENT 2 - AUTHORIZED USE(S) AND LICENSE CONDITIONS



LICENSE NUMBER MI073-26

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 dated April 7, 1981, signed by Mike Funk, Hospital Administrator;
- * Letter dated December 29, 1994, signed by Chris Gilbert, R.T., CNMT, Radiology Manager;
- * Letters dated September 15, and December 5, 1995, both signed by Chris Gilbert, R.T., CNMT, and Sonia Jackson, Radiology Manager;
- * Letter with attachments dated March 26, 1996, signed by Chris Gilbert, R.T., CNMT;
- * Letter dated December 2, 1996, signed by Sonia Jackson, RTR, Department Administrator;
- * Letter dated December 2, 1997, signed by Cubazell C. Wilmarth, Radiology Manager;
- * Letter dated March 2, 1998, signed by Chris Gilbert, R. T., CNMT;
- * Letter with attachment dated March 22, 2001, and telefax dated March 28, 2001, both signed by Stephen M. Glick, Radiology Manager;
- * Letter with attachments dated April 20, 2001, signed by Stephen M. Glick, RSO;
- * Letter with attachments dated July 12, 2002, signed by Joseph Valdez, Director of Radiology.





NOTICE TO EMPLOYEES
STANDARDS FOR PROTECTION AGAINST RADIATION
 (Part 4 20.3 NMAC)
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS
 (Part 10 20.3 NMAC)



State of New Mexico

Environment Department

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is either licensed or registered to utilize sources of radiation in accordance with the New Mexico Radiation Protection Regulations (20.3 NMAC).

Your employer is required to:

- Apply the regulations to work involving sources of radiation.
- Post or make available to you a copy of the regulations, license, and operating procedures that apply to work you are engaged in, and explain their provisions to you; post Notices of Violation involving radiological working conditions and orders.

If a company violates the requirements, it can be fined or have its license modified, suspended or revoked.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the regulations and the operating procedures that apply to the work you do. You should observe their provisions for you own protection and the protection of your co-workers. If you observe a violation, you should report it.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

If you work where personnel monitoring is required, your employer must:

- Give you a written report if you receive an exposure in excess of any limit as set forth in the regulations or in the license,
- Advise you of your dose annually, and
- Give you a written report of your radiation exposure upon termination of your employment.

NMED 045 Revised 1/2002

INSPECTIONS

All licensed and registered activities are subject to inspection by representatives of the Environment Department. During inspections, Department inspectors may confer privately with workers.

A worker, or representative of workers, may request an inspection by sending a signed notice of the alleged violation of the Act, regulations, or license condition.

CONTACTING THE RADIATION CONTROL BUREAU

You can contact the Radiation Control Bureau of the New Mexico Environment Department at the address and phone number listed below:

RADIATION CONTROL BUREAU

1190 St. Francis, 87505
 P.O. Box 26110, 87502-6110
 Santa Fe, New Mexico
 Telephone (505) 476-3236
 Fax (505) 476-3232

..... **POSTING REQUIREMENT**

Copies of this notice must be posted in a sufficient number of places to permit employees working in or frequenting any portion of a restricted area to observe a copy.

Dec 11 2007 9:47AM

ESPRANOLA XRRY DEPT

5057531534

P. 11



W.A. Foote Memorial Hospital
205 North East Avenue
Jackson, MI 49201

RE: Amendment for adding and removing Authorized Users

Dear Randy:

Enclosed please find the letter to the NRC for the addition of Dr. Asad and the removal of Dr. Renner as authorized users to your NRC license. The following steps need to be taken for completion.

1. Review carefully and be sure all information is correct. Retype or copy cover letter onto your facility letterhead.
2. Executive management (VP or higher) should sign the letter.
3. Make two (2) copies, including the New Mexico license listing Dr. Asad. These will go to the NRC. **Keep the original and file in the blue, MPC, license binder in the nuclear medicine department.**
4. Mail both sets of the signed copies to the following address: **Federal Express or U.P.S. is advised.**

**United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352**

If you have any questions, please contact me at (734) 662-3197.

Sincerely,

Laura M. Luna, B.S.
Physics Consultant

Enclosures

2309 Shelby Avenue ✱
Drive
Ann Arbor, MI 48103
(734) 662-9224 Fax
(734) 662-3197

70 E. 91st Street, Suite 10 ✱
Indianapolis, IN 46240
(317) 581-1931 Fax
(317) 581-1911

1780 E. Logan Avenue ✱
Salt Lake City, UT 84108
(801) 467-8774 Office & Fax

N7375 Crystal Ridge
Beaver Dam, WI 53916
(920) 885-9872 Fax
(920) 885-9870

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City Jackson State Mi ZIP 49202

2 Your Internal Billing Reference

3 To Recipient's Name

Company United States Nuclear Reg. Comm.

Address 2443 Warrenville Rd.

Address Suite 210

City Lisle State IL ZIP 60532



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5 Packaging
6 FedEx Envelope* 2 1

6 Special Handling
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